

**Annex I**  
**List of nationally authorised medicinal products**

| <b>Member State<br/>EU/EEA</b> | <b>Marketing<br/>authorisation<br/>holder</b> | <b>Product name</b>                  | <b>INN/Active<br/>substance</b> | <b>Strength</b> | <b>Pharmaceutical form</b>                          | <b>Route of<br/>administration</b> |
|--------------------------------|-----------------------------------------------|--------------------------------------|---------------------------------|-----------------|-----------------------------------------------------|------------------------------------|
| Austria                        | +pharma<br>Arzneimittel GmbH                  | Azithromycin<br>+pharma              | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Austria                        | 1a Pharma GmbH                                | Azithromycin 1a<br>Pharma            | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Austria                        | Dr. Friedrich Eberth<br>Arzneimittel GmbH     | Azithromycin Dr.<br>Friedrich Eberth | Azithromycin                    | 1mg/ml          | powder for concentrate<br>for solution for infusion | intravenous use                    |
| Austria                        | Genericon Pharma<br>Gesellschaft M.B.H.       | Azithromycin<br>Genericon            | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Austria                        | Krka, d.d., Novo<br>Mesto                     | Azithromycin Krka                    | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Austria                        | Pfizer Corporation<br>Austria Ges.M.B.H.      | Zithromax                            | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension                       | oral use                           |
| Austria                        | Pfizer Corporation<br>Austria Ges.M.B.H.      | Zithromax                            | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet                                  | oral use                           |
| Austria                        | Pfizer Corporation<br>Austria Ges.M.B.H.      | Zithromax I.V.                       | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion                 | intravenous use                    |
| Austria                        | Sandoz GmbH                                   | Azithromycin<br>Sandoz               | Azithromycin<br>Dihydrate       | 41.92mg/ml      | powder for oral<br>suspension                       | oral use                           |
| Austria                        | Sandoz GmbH                                   | Azithromycin<br>Sandoz               | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Austria                        | Stada Arzneimittel<br>GmbH                    | Azithromycin Stada                   | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension                       | oral use                           |
| Austria                        | Stada Arzneimittel<br>GmbH                    | Azithromycin Stada                   | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Austria                        | Teva B.V                                      | Azithromycin<br>Ratiopharm           | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |

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|--------------------------------|-----------------------------------------------|-------------------------|---------------------------------|-----------------|-----------------------------------------------------|------------------------------------|
| Belgium                        | Aurobindo N.V.                                | Azithromycin AB         | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Belgium                        | Aurobindo N.V.                                | Azithromycin AB         | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Belgium                        | Eurogenerics<br>N.V./S.A.                     | Azithromycine Eg        | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Belgium                        | Eurogenerics<br>N.V./S.A.                     | Azithromycine Eg        | Azithromycin<br>Monohydrate     | 512mg           | film-coated tablet                                  | oral use                           |
| Belgium                        | Eurogenerics<br>N.V./S.A.                     | Azithromycine Eg        | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension                       | oral use                           |
| Belgium                        | Eurogenerics<br>N.V./S.A.                     | Azithromycine Eg        | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Belgium                        | Pfizer S.A.                                   | Zitromax                | Azithromycin                    | 100mg/ml        | powder for concentrate<br>for solution for infusion | intravenous use                    |
| Belgium                        | Pfizer S.A.                                   | Zitromax                | Azithromycin<br>Dihydrate       | 262.01mg        | film-coated tablet                                  | oral use                           |
| Belgium                        | Pfizer S.A.                                   | Zitromax                | Azithromycin<br>Dihydrate       | 628.84mg        | film-coated tablet                                  | oral use                           |
| Belgium                        | Pfizer S.A.                                   | Zitromax                | Azithromycin<br>Dihydrate       | 524.03mg        | film-coated tablet                                  | oral use                           |
| Belgium                        | Pfizer S.A.                                   | Zitromax                | Azithromycin<br>Dihydrate       | 50.08mg         | powder for oral<br>suspension                       | oral use                           |
| Belgium                        | Sandoz N.V.                                   | Azithromycine<br>Sandoz | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Belgium                        | Sandoz N.V.                                   | Azithromycine<br>Sandoz | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |

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|--------------------------------|-----------------------------------------------|-------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Belgium                        | Sandoz N.V.                                   | Azithromycine<br>Sandoz | Azithromycin<br>Dihydrate       | 209.6mg/5ml     | powder for oral<br>suspension       | oral use                           |
| Belgium                        | Teva Pharma<br>Belgium N.V./S.A               | Azithromycine Teva      | Azithromycin<br>Dihydrate       | 262.055mg       | film-coated tablet                  | oral use                           |
| Belgium                        | Teva Pharma<br>Belgium N.V./S.A               | Azithromycine Teva      | Azithromycin<br>Dihydrate       | 524.109mg       | film-coated tablet                  | oral use                           |
| Belgium                        | Teva Pharma<br>Belgium N.V./S.A               | Azithromycin Teva       | Azithromycin<br>Dihydrate       | 262.055mg       | film-coated tablet                  | oral use                           |
| Bulgaria                       | Antibiotic-Razgrad<br>AD                      | Азитромицин ABR         | Azithromycin                    | 500mg           | capsule, hard                       | oral use                           |
| Bulgaria                       | Chemax Pharma Ltd                             | Зетрум                  | Azithromycin                    | 100mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Bulgaria                       | Chemax Pharma Ltd                             | Зетрум                  | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Bulgaria                       | Krka, d.d., Novo<br>Mesto                     | Азибиот                 | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension       | oral use                           |
| Bulgaria                       | Krka, d.d., Novo<br>Mesto                     | Азибиот                 | Azithromycin                    | 20mg/ml         | powder for oral<br>suspension       | oral use                           |
| Bulgaria                       | Krka, d.d., Novo<br>Mesto                     | Азибиот                 | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Bulgaria                       | Krka, d.d., Novo<br>Mesto                     | Азибиот                 | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Bulgaria                       | Nobel Pharma Ltd.                             | Азакс                   | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Bulgaria                       | S.C. Rompharm<br>Company S.r.l.               | Азитромицин<br>Ромфарм  | Azithromycin                    | 500mg           | powder for solution for<br>infusion | intravenous use                    |

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|--------------------------------|-----------------------------------------------|------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Bulgaria                       | Teva B.V                                      | Сумамед                | Azithromycin                    | 500mg           | powder for solution for<br>infusion | intravenous use                    |
| Bulgaria                       | Teva B.V                                      | Сумамед                | Azithromycin                    | 250mg           | capsule, hard                       | oral use                           |
| Bulgaria                       | Teva B.V                                      | Сумамед                | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Bulgaria                       | Teva B.V                                      | Сумамед Сироп          | Azithromycin                    | 100mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Bulgaria                       | Teva B.V                                      | Сумамед Форте<br>Сироп | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Bulgaria                       | Zentiva, K.S.                                 | Азатрил                | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Bulgaria                       | Zentiva, K.S.                                 | Азитрокс               | Azithromycin<br>Dihydrate       | 262mg           | film-coated tablet                  | oral use                           |
| Bulgaria                       | Zentiva, K.S.                                 | Азатрил                | Azithromycin                    | 100mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Bulgaria                       | Zentiva, K.S.                                 | Азатрил                | Azithromycin                    | 250mg           | capsule, hard                       | oral use                           |
| Bulgaria                       | Zentiva, K.S.                                 | Азитрокс               | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Croatia                        | Belupo d.d.                                   | Azitromicin Belupo     | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Croatia                        | Belupo d.d.                                   | Azitromicin Belupo     | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Croatia                        | Jadran-Galenski<br>Laboratorij d.d.           | Makromicin             | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |

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|--------------------------------|-----------------------------------------------|------------------------|---------------------------------|-----------------|-----------------------------------------------------|------------------------------------|
| Croatia                        | Krka-Farma d.o.o.                             | Azibiot                | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension                       | oral use                           |
| Croatia                        | Krka-Farma d.o.o.                             | Azibiot                | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Croatia                        | Krka-Farma d.o.o.                             | Azibiot                | Azithromycin                    | 20mg/ml         | powder for oral<br>suspension                       | oral use                           |
| Croatia                        | Pharmas d.o.o.                                | Azitromicin<br>Pharmas | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Croatia                        | Pharmas d.o.o.                                | Azitromicin<br>Pharmas | Azithromycin                    | 100mg/ml        | powder for concentrate<br>for solution for infusion | intravenous use                    |
| Croatia                        | Pliva Hrvatska<br>d.o.o.                      | Sumamed 1200           | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension                       | oral use                           |
| Croatia                        | Pliva Hrvatska<br>d.o.o.                      | Sumamed                | Azithromycin                    | 250mg           | capsule, hard                                       | oral use                           |
| Croatia                        | Pliva Hrvatska<br>d.o.o.                      | Sumamed                | Azithromycin                    | 125mg           | film-coated tablet                                  | oral use                           |
| Croatia                        | Pliva Hrvatska<br>d.o.o.                      | Sumamed                | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Croatia                        | Pliva Hrvatska<br>d.o.o.                      | Azimed                 | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Croatia                        | Pliva Hrvatska<br>d.o.o.                      | Sumamed                | Azithromycin                    | 500mg           | dispersible tablet                                  | oral use                           |
| Croatia                        | Pliva Hrvatska<br>d.o.o.                      | Sumamed                | Azithromycin                    | 100mg/5ml       | powder for oral<br>suspension                       | oral use                           |
| Croatia                        | Pliva Hrvatska<br>d.o.o.                      | Sumamed                | Azithromycin                    | 500mg           | powder for concentrate<br>for solution for infusion | intravenous use                    |

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|--------------------------------|-----------------------------------------------|-----------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Croatia                        | Pliva Hrvatska<br>d.o.o.                      | Sumamed 1500                | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Croatia                        | Pliva Hrvatska<br>d.o.o.                      | Sumamed Forte               | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Croatia                        | Pliva Hrvatska<br>d.o.o.                      | Azimed                      | Azithromycin                    | 250mg           | capsule, hard                       | oral use                           |
| Croatia                        | Sandoz d.o.o.                                 | Azitromicin Sandoz          | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Croatia                        | Sandoz d.o.o.                                 | Azitromicin Forte<br>Sandoz | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Croatia                        | Sandoz d.o.o.                                 | Azitromicin Sandoz          | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Cyprus                         | Altan<br>Pharmaceuticals<br>S.A.              | Azithromycin Altan          | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion | intravenous use                    |
| Cyprus                         | Iasis Pharma                                  | Bezanin                     | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Cyprus                         | Jubilant<br>Pharmaceuticals NV                | Azithromycin<br>Jubilant    | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Cyprus                         | Jubilant<br>Pharmaceuticals NV                | Azithromycin<br>Jubilant    | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Cyprus                         | Pfizer Hellas A.E.                            | Zithromax                   | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion | intravenous use                    |
| Cyprus                         | Pfizer Hellas A.E.                            | Zithromax                   | Azithromycin<br>Dihydrate       | 209.64mg/5ml    | powder for oral<br>suspension       | oral use                           |
| Cyprus                         | Rafarm SA                                     | Razimax                     | Azithromycin                    | 600mg           | film-coated tablet                  | oral use                           |

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|--------------------------------|-----------------------------------------------|---------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Cyprus                         | Rafarm SA                                     | Razimax             | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Cyprus                         | Sapiens<br>Pharmaceuticals Ltd                | Azithran            | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Cyprus                         | Verisfield S.M.S.A                            | Zinfect             | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Cyprus                         | Verisfield S.M.S.A                            | Zinfect             | Azithromycin                    | 600mg           | film-coated tablet                  | oral use                           |
| Cyprus                         | Verisfield S.M.S.A                            | Zinfect             | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Czech Republic                 | Mylan Ireland<br>Limited                      | Azitromycin Mylan   | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Czech Republic                 | Sandoz GmbH                                   | Azitromycin Sandoz  | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Czech Republic                 | Sandoz GmbH                                   | Azitromycin Sandoz  | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Czech Republic                 | Teva<br>Pharmaceuticals CR,<br>s.r.o.         | SUMAMED             | Azithromycin                    | 125mg           | film-coated tablet                  | oral use                           |
| Czech Republic                 | Teva<br>Pharmaceuticals CR,<br>s.r.o.         | SUMAMED             | Azithromycin                    | 500mg           | powder for solution for<br>infusion | intravenous use                    |
| Czech Republic                 | Teva<br>Pharmaceuticals CR,<br>s.r.o.         | SUMAMED             | Azithromycin                    | 20mg/ml         | powder for oral<br>suspension       | oral use                           |



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|--------------------------------|-----------------------------------------------|--------------------------|---------------------------------|-----------------|-----------------------------------------------------|------------------------------------|
| Czech Republic                 | Teva<br>Pharmaceuticals CR,<br>s.r.o.         | SUMAMED                  | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Czech Republic                 | Teva<br>Pharmaceuticals CR,<br>s.r.o.         | SUMAMED FORTE            | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension                       | oral use                           |
| Czech Republic                 | Teva<br>Pharmaceuticals CR,<br>s.r.o.         | SUMAMED                  | Azithromycin                    | 250mg           | capsule, hard                                       | oral use                           |
| Czech Republic                 | Zentiva, k.s.                                 | Azitrox                  | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Denmark                        | Jubilant<br>Pharmaceuticals NV                | Azithromycin<br>Jubilant | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Denmark                        | Jubilant<br>Pharmaceuticals NV                | Azithromycin<br>Jubilant | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Denmark                        | Krka, d.d., Novo<br>Mesto                     | Azithromycin Krka        | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Denmark                        | Macure Pharma ApS                             | Amzolynic                | Azithromycin                    | 500mg           | powder for concentrate<br>for solution for infusion | intravenous use                    |
| Denmark                        | Mylan AB                                      | Azithromycin Mylan       | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Denmark                        | Pfizer ApS                                    | Zitromax                 | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Denmark                        | Pfizer ApS                                    | Zitromax                 | Azithromycin                    | 100mg/ml        | powder for concentrate<br>for solution for infusion | intravenous use                    |
| Denmark                        | Pfizer ApS                                    | Zitromax                 | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension                       | oral use                           |

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|--------------------------------|-----------------------------------------------|--------------------------|---------------------------------|-----------------|-------------------------------|------------------------------------|
| Denmark                        | Pfizer ApS                                    | Zitromax                 | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Denmark                        | Sandoz A/S                                    | Azithromycin<br>Sandoz   | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Denmark                        | Stada Arzneimittel<br>AG                      | Azithromycin Stada       | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension | oral use                           |
| Denmark                        | Stada Arzneimittel<br>AG                      | Azithromycin Stada       | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Denmark                        | Teva B.V                                      | Azithromycin Teva        | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Estonia                        | Grindeks                                      | Azithromycin<br>Grindeks | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Estonia                        | Krka, d.d., Novo<br>Mesto                     | Azithromycin Krka        | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Estonia                        | Krka, d.d., Novo<br>Mesto                     | Azithromycin Krka        | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Estonia                        | Rivopharm Ltd                                 | Zylumit                  | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Estonia                        | Sandoz GmbH                                   | Azithromycin<br>Sandoz   | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Estonia                        | Teva Pharma B.V.                              | Sumamed Forte            | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension | oral use                           |
| Estonia                        | Teva Pharma B.V.                              | Sumamed                  | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Estonia                        | Teva Pharma B.V.                              | Sumamed                  | Azithromycin                    | 250mg           | capsule, hard                 | oral use                           |

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|--------------------------------|-----------------------------------------------|------------------------|---------------------------------|-----------------|-----------------------------------------------------|------------------------------------|
| Estonia                        | Zentiva, K.S.                                 | Azitrox                | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Finland                        | Krka, d.d., Novo Mesto                        | Azithromycin Krka      | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Finland                        | Krka, d.d., Novo Mesto                        | Azithromycin Krka      | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Finland                        | Macure Pharma ApS                             | Amzolynic              | Azithromycin                    | 500mg           | powder for concentrate<br>for solution for infusion | intravenous use                    |
| Finland                        | Orion Corporation                             | Azithromycin Orion     | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Finland                        | Pfizer Oy                                     | Zithromax              | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension                       | oral use                           |
| Finland                        | Pfizer Oy                                     | Zithromax              | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Finland                        | Pfizer Oy                                     | Zithromax Iv           | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion                 | intravenous use                    |
| Finland                        | Pfizer Oy                                     | Zithromax              | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Finland                        | Sandoz A/S                                    | Azithromycin<br>Sandoz | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Finland                        | Sandoz A/S                                    | Azithromycin<br>Sandoz | Azithromycin<br>Dihydrate       | 209.6mg/5ml     | powder for oral<br>suspension                       | oral use                           |
| Finland                        | Sandoz A/S                                    | Azithromycin<br>Sandoz | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Finland                        | Stada Arzneimittel<br>AG                      | Azithromycin Stada     | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |

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|--------------------------------|-----------------------------------------------|----------------------------------|---------------------------------|-----------------|----------------------------|------------------------------------|
| Finland                        | Stada Arzneimittel<br>AG                      | Azithromycin Stada               | Azithromycin                    | 250mg           | film-coated tablet         | oral use                           |
| Finland                        | Teva Sweden AB                                | Azithromycin<br>Ratiopharm       | Azithromycin                    | 500mg           | film-coated tablet         | oral use                           |
| Finland                        | Teva Sweden AB                                | Azithromycin<br>Ratiopharm       | Azithromycin                    | 250mg           | film-coated tablet         | oral use                           |
| France                         | Arrow Generiques                              | Azithromycine<br>Arrow Lab       | Azithromycin<br>Dihydrate       | 524mg           | film-coated tablet         | oral use                           |
| France                         | Arrow Generiques                              | Azithromycine<br>Arrow           | Azithromycin                    | 250mg           | film-coated tablet         | oral use                           |
| France                         | Arrow Generiques                              | Azithromycine<br>Arrow Lab       | Azithromycin<br>Dihydrate       | 262mg           | film-coated tablet         | oral use                           |
| France                         | Biogaran                                      | Azithromycine Bgr                | Azithromycin                    | 250mg           | film-coated tablet         | oral use                           |
| France                         | Biogaran                                      | Azithromycine<br>Biogaran        | Azithromycin                    | 250mg           | film-coated tablet         | oral use                           |
| France                         | Bluepharma<br>Indústria<br>Farmacêutica S.A.  | Azithromycine<br>Bluepharma      | Azithromycin                    | 250mg           | film-coated tablet         | oral use                           |
| France                         | Cristers                                      | Azithromycine<br>Cristers        | Azithromycin<br>Dihydrate       | 262.05mg        | film-coated tablet         | oral use                           |
| France                         | Cristers                                      | Azithromycine<br>Cristers Pharma | Azithromycin                    | 250mg           | film-coated tablet         | oral use                           |
| France                         | Eg Labo<br>Laboratoires<br>Eurogenerics       | Azithromycine Eg                 | Azithromycin                    | 250mg           | film-coated tablet         | oral use                           |

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|--------------------------------|-----------------------------------------------|----------------------------------|---------------------------------|-----------------|-------------------------------|------------------------------------|
| France                         | Evolupharm                                    | Azithromycine<br>Evolugen        | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| France                         | Krka, d.d., Novo<br>Mesto                     | Azithromycine Krka               | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| France                         | Pfizer Holding<br>France                      | Zithromax Enfants                | Azithromycin<br>Dihydrate       | 41.92mg/ml      | powder for oral<br>suspension | oral use                           |
| France                         | Pfizer Holding<br>France                      | Azadose                          | Azithromycin<br>Dihydrate       | 628.93mg        | film-coated tablet            | oral use                           |
| France                         | Pfizer Holding<br>France                      | Zithromax<br>Monodose            | Azithromycin<br>Dihydrate       | 262.05mg        | film-coated tablet            | oral use                           |
| France                         | Pfizer Holding<br>France                      | Azithromycine<br>Pfizer          | Azithromycin<br>Dihydrate       | 262.05mg        | film-coated tablet            | oral use                           |
| France                         | Pfizer Holding<br>France                      | Zithromax                        | Azithromycin<br>Dihydrate       | 262.05mg        | film-coated tablet            | oral use                           |
| France                         | Sandoz                                        | Azithromycine<br>Sandoz          | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| France                         | Sandoz                                        | Azithromycine<br>Monodose Sandoz | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| France                         | Teva Santé                                    | Azithromycine Teva               | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| France                         | Tonipharm                                     | Ordipha                          | Azithromycin                    | 500mg           | dispersible tablet            | oral use                           |
| France                         | Viartis Sante                                 | Azithromycine<br>Viartis         | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| France                         | Zentiva France                                | Azithromycine<br>Zentiva         | Azithromycin<br>Dihydrate       | 262.05mg        | film-coated tablet            | oral use                           |

| <b>Member State<br/>EU/EEA</b> | <b>Marketing<br/>authorisation<br/>holder</b> | <b>Product name</b>        | <b>INN/Active<br/>substance</b> | <b>Strength</b> | <b>Pharmaceutical form</b>    | <b>Route of<br/>administration</b> |
|--------------------------------|-----------------------------------------------|----------------------------|---------------------------------|-----------------|-------------------------------|------------------------------------|
| France                         | Zydus France                                  | Azithromycine<br>Zydus     | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Germany                        | 1 A Pharma GmbH                               | Azithromycin 1 A<br>Pharma | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension | oral use                           |
| Germany                        | 1 A Pharma GmbH                               | Azithromycin 500           | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Germany                        | 1 A Pharma GmbH                               | Azithromycin 250           | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Germany                        | Abz-Pharma GmbH                               | Azithromycin Abz           | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Germany                        | Abz-Pharma GmbH                               | Azithromycin Abz           | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Germany                        | Aliud Pharma GmbH                             | Azithromycin Al            | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Germany                        | Aliud Pharma GmbH                             | Azithromycin Al            | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Germany                        | Aristo Pharma<br>GmbH (Art 57)                | Azithromycin Aristo        | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Germany                        | Aristo Pharma<br>GmbH (Art 57)                | Azithromycin Aristo        | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Germany                        | Bluepharma<br>Indústria<br>Farmacêutica S.A.  | Azithromycin<br>Bluepharma | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Germany                        | Bluepharma<br>Indústria<br>Farmacêutica S.A.  | Azithromycin<br>Bluepharma | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |

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|--------------------------------|-----------------------------------------------|--------------------------------------|---------------------------------|-----------------|-----------------------------------------------------|------------------------------------|
| Germany                        | Denk Pharma GmbH<br>& Co. KG                  | Azithromycin Denk                    | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Germany                        | Denk Pharma GmbH<br>& Co. KG                  | Azithromycin Denk                    | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Germany                        | Dr. Friedrich Eberth<br>Arzneimittel GmbH     | Azithromycin Dr.<br>Eberth           | Azithromycin                    | 1-2mg/ml        | powder for solution for<br>infusion                 | intravenous use                    |
| Germany                        | Dr. Friedrich Eberth<br>Arzneimittel GmbH     | Azithromycin Dr.<br>Friedrich Eberth | Azithromycin                    | 100mg/ml        | powder for concentrate<br>for solution for infusion | intravenous use                    |
| Germany                        | Dr. Friedrich Eberth<br>Arzneimittel GmbH     | Azithromycin<br>Friedrich Eberth     | Azithromycin                    | 1mg/ml          | powder for concentrate<br>for solution for infusion | intravenous use                    |
| Germany                        | Hec Pharm GmbH                                | Azithromycin Hec<br>Pharm            | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension                       | oral use                           |
| Germany                        | Hec Pharm GmbH                                | Azithromycin Hec                     | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Germany                        | Hec Pharm GmbH                                | Azithromycin Hec                     | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet                                  | oral use                           |
| Germany                        | Heumann Pharma<br>GmbH & Co.<br>Generica KG   | Azithromycin<br>Heumann              | Azithromycin<br>Dihydrate       | 262.05mg        | film-coated tablet                                  | oral use                           |
| Germany                        | Heumann Pharma<br>GmbH & Co.<br>Generica KG   | Azithromycin<br>Heumann              | Azithromycin<br>Dihydrate       | 524mg           | film-coated tablet                                  | oral use                           |
| Germany                        | Hexal AG                                      | Azithromycin Hexal                   | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Germany                        | Hexal AG                                      | Azithromycin Hexal                   | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |

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|--------------------------------|-----------------------------------------------|----------------------------|---------------------------------|-----------------|-------------------------------|------------------------------------|
| Germany                        | Hexal AG                                      | Azithromycin Hexal         | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension | oral use                           |
| Germany                        | Mylan Germany<br>GmbH                         | Azithromycin Dura          | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Germany                        | Mylan Germany<br>GmbH                         | Azithromycin Dura          | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Germany                        | Pfizer Pharma<br>GmbH                         | Zithromax                  | Azithromycin<br>Dihydrate       | 262.05mg        | film-coated tablet            | oral use                           |
| Germany                        | Pfizer Pharma<br>GmbH                         | Ultrleon                   | Azithromycin<br>Dihydrate       | 628.93mg        | film-coated tablet            | oral use                           |
| Germany                        | Pfizer Pharma<br>GmbH                         | Zithromax                  | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet            | oral use                           |
| Germany                        | Pfizer Pharma<br>GmbH                         | Zithromax<br>Trockensaft   | Azithromycin<br>Dihydrate       | 209.6mg/5ml     | powder for oral<br>suspension | oral use                           |
| Germany                        | Ratiopharm GmbH                               | Azithromycin<br>Ratiopharm | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Germany                        | Ratiopharm GmbH                               | Azithromycin<br>Ratiopharm | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension | oral use                           |
| Germany                        | Ratiopharm GmbH                               | Azithromycin<br>Ratiopharm | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Germany                        | Stadapharm GmbH                               | Azithromycin Stada         | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Germany                        | Stadapharm GmbH                               | Azithromycin Stada         | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Germany                        | Tad Pharma GmbH                               | Azithromycin Tad           | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |



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|--------------------------------|-----------------------------------------------|---------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Germany                        | Tad Pharma GmbH                               | Azithromycin Tad    | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Germany                        | Teva GmbH                                     | Azi-Teva            | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Germany                        | Teva GmbH                                     | Azi-Teva            | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Germany                        | Teva GmbH                                     | Azi-Teva            | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Greece                         | Anfarm Hellas SA                              | Zithrotel           | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion | intravenous use                    |
| Greece                         | Anfarm Hellas SA                              | Zithrotel           | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Greece                         | Anfarm Hellas SA                              | Zithrotel           | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Greece                         | Anfarm Hellas SA                              | Zithrotel           | Azithromycin                    | 600mg           | film-coated tablet                  | oral use                           |
| Greece                         | Balu S.A                                      | Zithroplus          | Azithromycin                    | 500mg           | tablet                              | oral use                           |
| Greece                         | Cross<br>Pharmaceuticals<br>P.C.              | Azibactron          | Azithromycin                    | 600mg           | film-coated tablet                  | oral use                           |
| Greece                         | Cross<br>Pharmaceuticals<br>P.C.              | Azibactron          | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Greece                         | Cross<br>Pharmaceuticals<br>P.C.              | Azibactron          | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |

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|--------------------------------|-----------------------------------------------|---------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Greece                         | Fos Farmakeftiki<br>IKE                       | Zithro-Due          | Azithromycin                    | 500mg           | tablet                              | oral use                           |
| Greece                         | Help Abee                                     | Zithroxyn           | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Greece                         | Iasis Pharma                                  | Bezanin             | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Greece                         | Iasis Pharma                                  | Bezanin             | Azithromycin                    | 600mg           | film-coated tablet                  | oral use                           |
| Greece                         | Iasis Pharma                                  | Bezanin             | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Greece                         | Lyofin Ltd, Greece                            | Zithrobest          | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion | intravenous use                    |
| Greece                         | Lyofin Ltd, Greece                            | Zithrobest          | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Greece                         | Medilat Medical<br>Pharmaceutical<br>Products | Azytan              | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Greece                         | Pfizer Hellas A.E.                            | Zithromax           | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion | intravenous use                    |
| Greece                         | Pfizer Hellas A.E.                            | Zithromax           | Azithromycin                    | 250mg           | capsule, hard                       | oral use                           |
| Greece                         | Pfizer Hellas A.E.                            | Zithromax           | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Greece                         | Pfizer Hellas A.E.                            | Zithromax           | Azithromycin<br>Dihydrate       | 209.64mg/5ml    | powder for oral<br>suspension       | oral use                           |
| Greece                         | Pfizer Hellas A.E.                            | Zithromax           | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |

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|--------------------------------|---------------------------------------------------|---------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Greece                         | Rafarm SA                                         | Razimax                   | Azithromycin                    | 600mg           | film-coated tablet                  | oral use                           |
| Greece                         | Rafarm SA                                         | Razimax                   | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Greece                         | Rafarm SA                                         | Alzirax                   | Azithromycin                    | 600mg           | film-coated tablet                  | oral use                           |
| Greece                         | Sja Pharm Ltd                                     | Disithrom                 | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Greece                         | Syndesmos S.A. -<br>Pharmaceutical<br>Wholesalers | Azithromycin<br>Syndesmos | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Greece                         | Velka Hellas S.A.                                 | Ciroz                     | Azithromycin                    | 600mg           | film-coated tablet                  | oral use                           |
| Greece                         | Venifar Ltd                                       | Azifarm                   | Azithromycin                    | 600mg           | film-coated tablet                  | oral use                           |
| Greece                         | Venifar Ltd                                       | Azifarm                   | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Greece                         | Verisfield S.M.S.A                                | Azivirus                  | Azithromycin                    | 600mg           | film-coated tablet                  | oral use                           |
| Greece                         | Verisfield S.M.S.A                                | Zinfect                   | Azithromycin                    | 500mg           | powder for solution for<br>infusion | intravenous use                    |
| Greece                         | Verisfield S.M.S.A                                | Azivirus                  | Azithromycin<br>Dihydrate       | 262mg           | film-coated tablet                  | oral use                           |
| Greece                         | Verisfield S.M.S.A                                | Zinfect                   | Azithromycin                    | 600mg           | film-coated tablet                  | oral use                           |
| Greece                         | Verisfield S.M.S.A                                | Zinfect                   | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |

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|--------------------------------|-----------------------------------------------|----------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Greece                         | Verisfield S.M.S.A                            | Zinfect                    | Azithromycin<br>Dihydrate       | 262mg           | film-coated tablet                  | oral use                           |
| Greece                         | Verisfield S.M.S.A                            | Azivirus                   | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Greece                         | Vian S.A.                                     | Azirox                     | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Greece                         | Vian S.A.                                     | Azirox                     | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Greece                         | Vian S.A.                                     | Azirox                     | Azithromycin                    | 600mg           | film-coated tablet                  | oral use                           |
| Greece                         | Vocate<br>Φαρμακευτική Αε                     | Azithromycin<br>Vocate     | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Greece                         | Vocate<br>Φαρμακευτική Αε                     | Azithromycin<br>Vocate     | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion | intravenous use                    |
| Greece                         | Zwitter<br>Pharmaceuticals<br>ΕΠΕ             | Azirutec                   | Azithromycin                    | 600mg           | film-coated tablet                  | oral use                           |
| Greece                         | Zwitter<br>Pharmaceuticals<br>ΕΠΕ             | Azirutec                   | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Hungary                        | 1 A Pharma GmbH                               | Azithromycin 1 A<br>Pharma | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Hungary                        | 1 A Pharma GmbH                               | Azithromycin 1 A<br>Pharma | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Hungary                        | Goodwill Pharma<br>Ltd                        | Azirowill                  | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |

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|--------------------------------|-----------------------------------------------|---------------------|---------------------------------|-----------------|--------------------------------------------------|------------------------------------|
| Hungary                        | Goodwill Pharma Ltd                           | Azirowill           | Azithromycin                    | 500mg           | film-coated tablet                               | oral use                           |
| Hungary                        | Jubilant Pharmaceuticals NV                   | Aziwill             | Azithromycin                    | 500mg           | film-coated tablet                               | oral use                           |
| Hungary                        | Jubilant Pharmaceuticals NV                   | Aziwill             | Azithromycin                    | 250mg           | film-coated tablet                               | oral use                           |
| Hungary                        | Krka, d.d., Novo Mesto                        | Azibiot             | Azithromycin                    | 250mg           | film-coated tablet                               | oral use                           |
| Hungary                        | Krka, d.d., Novo Mesto                        | Azibiot             | Azithromycin                    | 500mg           | film-coated tablet                               | oral use                           |
| Hungary                        | Sandoz GmbH                                   | Azi                 | Azithromycin                    | 500mg           | film-coated tablet                               | oral use                           |
| Hungary                        | Sandoz GmbH                                   | Azi                 | Azithromycin                    | 250mg           | film-coated tablet                               | oral use                           |
| Hungary                        | Sandoz Hungária Kft                           | Azithromycin Sandoz | Azithromycin Dihydrate          | 209.6mg/5ml     | powder for oral suspension                       | oral use                           |
| Hungary                        | Teva Gyógyszergyár Zrt                        | Zitrocin            | Azithromycin Dihydrate          | 524.109mg       | film-coated tablet                               | oral use                           |
| Hungary                        | Teva Gyógyszergyár Zrt                        | Sumamed             | Azithromycin                    | 500mg           | powder for concentrate for solution for infusion | intravenous use                    |
| Hungary                        | Teva Gyógyszergyár Zrt                        | Sumamed             | Azithromycin                    | 100mg/5ml       | powder for syrup                                 | oral use                           |
| Hungary                        | Teva Gyógyszergyár Zrt                        | Sumamed S           | Azithromycin Dihydrate          | 524.109mg       | film-coated tablet                               | oral use                           |
| Hungary                        | Teva Gyógyszergyár Zrt                        | Sumamed             | Azithromycin Dihydrate          | 262.05mg        | capsule, hard                                    | oral use                           |

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|--------------------------------|-----------------------------------------------|----------------------|---------------------------------|-----------------|--------------------------------------------------|------------------------------------|
| Hungary                        | Teva Gyógyszergyár Zrt                        | Sumamed              | Azithromycin                    | 500mg           | film-coated tablet                               | oral use                           |
| Hungary                        | Teva Gyógyszergyár Zrt                        | Sumamed Forte        | Azithromycin                    | 200mg/5ml       | powder for syrup                                 | oral use                           |
| Iceland                        | Dr. Friedrich Eberth Arzneimittel GmbH        | Azithromycin Eberth  | Azithromycin Dihydrate          | 524.03mg        | powder for solution for infusion                 | intravenous use                    |
| Iceland                        | Laboratorios Normon, S.A.                     | Azithromycin Normon  | Azithromycin                    | 500mg           | film-coated tablet                               | oral use                           |
| Iceland                        | Pfizer ApS                                    | Zitromax             | Azithromycin                    | 100mg/ml        | powder for concentrate for solution for infusion | intravenous use                    |
| Iceland                        | Pfizer ApS                                    | Zitromax             | Azithromycin                    | 40mg/ml         | powder for oral suspension                       | oral use                           |
| Iceland                        | Pfizer ApS                                    | Zitromax             | Azithromycin                    | 500mg           | film-coated tablet                               | oral use                           |
| Iceland                        | Pfizer ApS                                    | Zitromax             | Azithromycin                    | 250mg           | film-coated tablet                               | oral use                           |
| Iceland                        | Stada Arzneimittel AG                         | Azithromycin Stada   | Azithromycin                    | 200mg/5ml       | powder for oral suspension                       | oral use                           |
| Iceland                        | Stada Arzneimittel AG                         | Azithromycin Stada   | Azithromycin                    | 500mg           | film-coated tablet                               | oral use                           |
| Ireland                        | Clonmel Healthcare Ltd.                       | Azithromycin Clonmel | Azithromycin                    | 250mg           | film-coated tablet                               | oral use                           |
| Ireland                        | European Regulatory Affairs T/A Ivowen        | Zedbac               | Azithromycin                    | 100mg/ml        | powder for concentrate for solution for infusion | intravenous use                    |
| Ireland                        | Krka, d.d., Novo Mesto                        | Azithromycin Krka    | Azithromycin                    | 250mg           | film-coated tablet                               | oral use                           |

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|--------------------------------|-----------------------------------------------|---------------------|---------------------------------|-----------------|------------------------------------------------------|------------------------------------|
| Ireland                        | Mcdermott<br>Laboratories Ltd                 | Azromax             | Azithromycin                    | 250mg           | film-coated tablet                                   | oral use                           |
| Ireland                        | Pfizer Healthcare<br>Ireland                  | Zithromax           | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension                        | oral use                           |
| Ireland                        | Pfizer Healthcare<br>Ireland                  | Zithromax           | Azithromycin                    | 250mg           | capsule, hard                                        | oral use                           |
| Ireland                        | Teva Pharma B.V.                              | Azithromycin Teva   | Azithromycin                    | 250mg           | film-coated tablet                                   | oral use                           |
| Italy                          | Accord Healthcare<br>S.L.U.                   | Azitromicina Accord | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet                                   | oral use                           |
| Italy                          | Agips Farmaceutici<br>S.r.l.                  | Portex              | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet                                   | oral use                           |
| Italy                          | Alfasigma S.P.A.                              | Trozocina           | Azithromycin<br>Dihydrate       | 524.1mg         | powder for solution for<br>infusion                  | intravenous use                    |
| Italy                          | Alfasigma S.P.A.                              | Trozocina           | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension                        | oral use                           |
| Italy                          | Alfasigma S.P.A.                              | Trozocina Avium     | Azithromycin<br>Dihydrate       | 628.93mg        | film-coated tablet                                   | oral use                           |
| Italy                          | Alfasigma S.P.A.                              | Trozocina           | Azithromycin                    | 500mg           | film-coated tablet                                   | oral use                           |
| Italy                          | Alfasigma S.P.A.                              | Trozocina           | Azithromycin<br>Dihydrate       | 262.05mg        | capsule, hard                                        | oral use                           |
| Italy                          | Alfasigma S.P.A.                              | Trozocina           | Azithromycin                    | 2g              | prolonged-release<br>granules for oral<br>suspension | oral use                           |
| Italy                          | Almus S.r.l.                                  | Azitromicina Almus  | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet                                   | oral use                           |

| <b>Member State<br/>EU/EEA</b> | <b>Marketing<br/>authorisation<br/>holder</b>                      | <b>Product name</b>          | <b>INN/Active<br/>substance</b> | <b>Strength</b> | <b>Pharmaceutical form</b>           | <b>Route of<br/>administration</b> |
|--------------------------------|--------------------------------------------------------------------|------------------------------|---------------------------------|-----------------|--------------------------------------|------------------------------------|
| Italy                          | Aurobindo Pharma<br>(Italia) S.r.l.                                | Azitromicina<br>Aurobindo    | Azithromycin                    | 500mg           | film-coated tablet                   | oral use                           |
| Italy                          | Doc Generici S.r.l.                                                | Azitromicina Doc<br>Generici | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet                   | oral use                           |
| Italy                          | Dymalife<br>Pharmaceutical<br>S.r.l.                               | Azeptin                      | Azithromycin                    | 500mg           | film-coated tablet                   | oral use                           |
| Italy                          | Eg S.P.A.                                                          | Azitromicina Eg<br>Stada     | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension        | oral use                           |
| Italy                          | Eg S.P.A.                                                          | Azitromicina Eg              | Azithromycin                    | 500mg           | film-coated tablet                   | oral use                           |
| Italy                          | Epifarma S.r.l.                                                    | Zitrobiotic                  | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet                   | oral use                           |
| Italy                          | S.F. Group S.r.l.                                                  | Azitroerre                   | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet                   | oral use                           |
| Italy                          | Genetic SpA                                                        | Azacid                       | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet                   | oral use                           |
| Italy                          | Inca-Pharm S.r.l.                                                  | Azylung                      | Azithromycin                    | 100mg/ml        | powder for solution for<br>injection | intravenous use                    |
| Italy                          | Ipso Pharma S.r.l.                                                 | Azitromicina Abc             | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet                   | oral use                           |
| Italy                          | Istituto Chimico<br>Internazionale Dr.<br>Giuseppe Rende<br>S.r.l. | Rezan                        | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet                   | oral use                           |
| Italy                          | Konpharma S.r.l.                                                   | Azitrox                      | Azithromycin<br>Dihydrate       | 524mg           | film-coated tablet                   | oral use                           |



| <b>Member State<br/>EU/EEA</b> | <b>Marketing<br/>authorisation<br/>holder</b> | <b>Product name</b>                | <b>INN/Active<br/>substance</b> | <b>Strength</b> | <b>Pharmaceutical form</b>       | <b>Route of<br/>administration</b> |
|--------------------------------|-----------------------------------------------|------------------------------------|---------------------------------|-----------------|----------------------------------|------------------------------------|
| Italy                          | Krka, d.d., Novo Mesto                        | Azitromicina Krka                  | Azithromycin                    | 40mg/ml         | powder for oral suspension       | oral use                           |
| Italy                          | Krka, d.d., Novo Mesto                        | Azitromicina Krka                  | Azithromycin                    | 500mg           | film-coated tablet               | oral use                           |
| Italy                          | Krka, d.d., Novo Mesto                        | Azitromicina Krka                  | Azithromycin                    | 250mg           | film-coated tablet               | oral use                           |
| Italy                          | Laboratorio Farmaceutico C.T. S.r.l.          | Batif                              | Azithromycin Dihydrate          | 524.1mg         | film-coated tablet               | oral use                           |
| Italy                          | Lanova Farmaceutici S.r.l.                    | Zitronova                          | Azithromycin Dihydrate          | 524.1mg         | film-coated tablet               | oral use                           |
| Italy                          | Aesculapius Farmaceutici S.r.l.               | Zitrogram                          | Azithromycin Dihydrate          | 524.1mg         | film-coated tablet               | oral use                           |
| Italy                          | Maven Pharma S.r.l.S.r.l.                     | Zindel                             | Azithromycin Dihydrate          | 524.1mg         | film-coated tablet               | oral use                           |
| Italy                          | Mylan S.P.A.                                  | Azitromicina Mylan                 | Azithromycin                    | 500mg           | film-coated tablet               | oral use                           |
| Italy                          | Mylan S.P.A.                                  | Azitromicina Mylan Generics Italia | Azithromycin Dihydrate          | 209.6mg/5ml     | powder for oral suspension       | oral use                           |
| Italy                          | Pfizer Italia S.r.l.S.r.l.                    | Zitromax                           | Azithromycin Dihydrate          | 524.1mg         | powder for solution for infusion | intravenous use                    |
| Italy                          | Pfizer Italia S.r.l.S.r.l.                    | Zitromax                           | Azithromycin Dihydrate          | 524.11mg        | film-coated tablet               | oral use                           |
| Italy                          | Pfizer Italia S.r.l.                          | Zitromax                           | Azithromycin Dihydrate          | 419.2mg         | powder for oral suspension       | oral use                           |
| Italy                          | Pfizer Italia S.r.l.S.r.l.                    | Zitromax                           | Azithromycin Dihydrate          | 314.4mg         | powder for oral suspension       | oral use                           |

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|--------------------------------|-----------------------------------------------|-------------------------|---------------------------------|-----------------|-------------------------------|------------------------------------|
| Italy                          | Pfizer Italia S.r.l.                          | Zitromax                | Azithromycin<br>Dihydrate       | 209.6mg         | powder for oral<br>suspension | oral use                           |
| Italy                          | Pfizer Italia S.r.l.                          | Zitromax                | Azithromycin<br>Dihydrate       | 157.2mg         | powder for oral<br>suspension | oral use                           |
| Italy                          | Pfizer Italia S.r.l.                          | Zitromax                | Azithromycin<br>Dihydrate       | 104.8mg         | powder for oral<br>suspension | oral use                           |
| Italy                          | Pfizer Italia S.r.l.                          | Zitromax                | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension | oral use                           |
| Italy                          | Pfizer Italia S.r.l.                          | Azitromicina Pfizer     | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension | oral use                           |
| Italy                          | Pfizer Italia S.r.l.                          | Zitromax Avium          | Azithromycin<br>Dihydrate       | 628.93mg        | film-coated tablet            | oral use                           |
| Italy                          | Pfizer Italia S.r.l.                          | Azitromicina Pfizer     | Azithromycin<br>Dihydrate       | 524.11mg        | film-coated tablet            | oral use                           |
| Italy                          | Pfizer Italia S.r.l.                          | Zitromax                | Azithromycin<br>Dihydrate       | 262.05mg        | capsule, hard                 | oral use                           |
| Italy                          | Pharmeg S.r.l.                                | Azitromicina<br>Pharmeg | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet            | oral use                           |
| Italy                          | Piam Farmaceutici<br>SpA                      | Azitredil               | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet            | oral use                           |
| Italy                          | Proge Farm S.r.l.                             | Aziprome                | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet            | oral use                           |
| Italy                          | S.F. Group S.r.l.                             | Macrozit                | Azithromycin<br>Dihydrate       | 524.11mg        | film-coated tablet            | oral use                           |
| Italy                          | S.F. Group S.r.l.                             | Zimacrol                | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet            | oral use                           |

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|--------------------------------|-----------------------------------------------|-----------------------------|---------------------------------|-----------------|-------------------------------|------------------------------------|
| Italy                          | S.F. Group S.r.l.                             | Tetris                      | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet            | oral use                           |
| Italy                          | Sandoz GmbH                                   | Azitromicina<br>Sandoz GmbH | Azithromycin<br>Dihydrate       | 41.92mg/ml      | powder for oral<br>suspension | oral use                           |
| Italy                          | Sandoz S.P.A.                                 | Azitromicina<br>Sandoz      | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Italy                          | So.Se.Pharm S.r.l.                            | Trozamil                    | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet            | oral use                           |
| Italy                          | Teva Italia S.r.l.                            | Azitromicina Teva<br>Italia | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension | oral use                           |
| Italy                          | Teva Italia S.r.l.                            | Azitromicina Teva           | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Italy                          | Teva Italia S.r.l.                            | Azitromicina Teva           | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Italy                          | Towa<br>Pharmaceutical<br>S.P.A.              | Azitromicina Pensa          | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet            | oral use                           |
| Italy                          | Zentiva Italia S.r.l.                         | Azitromicina<br>Zentiva     | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet            | oral use                           |
| Latvia                         | Krka, d.d., Novo<br>Mesto                     | Azibiot                     | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Latvia                         | Sandoz GmbH                                   | Azithromycin<br>Sandoz      | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Latvia                         | Teva Pharma B.V.                              | Sumamed                     | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Latvia                         | Teva Pharma B.V.                              | Sumamed                     | Azithromycin                    | 250mg           | capsule, hard                 | oral use                           |

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|--------------------------------|-----------------------------------------------|---------------------------|---------------------------------|-----------------|----------------------------|------------------------------------|
| Lithuania                      | Krka, d.d., Novo Mesto                        | Azibiot                   | Azithromycin                    | 40mg/ml         | powder for oral suspension | oral use                           |
| Lithuania                      | Krka, d.d., Novo Mesto                        | Azibiot                   | Azithromycin                    | 20mg/ml         | powder for oral suspension | oral use                           |
| Lithuania                      | Krka, d.d., Novo Mesto                        | Azibiot                   | Azithromycin                    | 500mg           | film-coated tablet         | oral use                           |
| Lithuania                      | Krka, d.d., Novo Mesto                        | Azibiot                   | Azithromycin                    | 250mg           | film-coated tablet         | oral use                           |
| Lithuania                      | Rivopharm Ltd                                 | Zylumit                   | Azithromycin                    | 500mg           | film-coated tablet         | oral use                           |
| Lithuania                      | Sandoz GmbH                                   | Azithromycin Sandoz       | Azithromycin                    | 500mg           | film-coated tablet         | oral use                           |
| Lithuania                      | Sia Ingen Pharma                              | Azithromycin Ingen Pharma | Azithromycin                    | 500mg           | film-coated tablet         | oral use                           |
| Lithuania                      | Teva Pharma B.V.                              | Azithromycin Teva         | Azithromycin                    | 500mg           | dispersible tablet         | oral use                           |
| Lithuania                      | Teva Pharma B.V.                              | Sumamed Forte             | Azithromycin                    | 200mg/5ml       | powder for oral suspension | oral use                           |
| Lithuania                      | Teva Pharma B.V.                              | Sumamed                   | Azithromycin                    | 500mg           | film-coated tablet         | oral use                           |
| Lithuania                      | Teva Pharma B.V.                              | Sumamed                   | Azithromycin                    | 250mg           | capsule, hard              | oral use                           |
| Lithuania                      | Zentiva, K.S.                                 | Azitrox                   | Azithromycin Dihydrate          | 524mg           | film-coated tablet         | oral use                           |
| Lithuania                      | Zentiva, K.S.                                 | Azitrox                   | Azithromycin                    | 250mg           | film-coated tablet         | oral use                           |

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|--------------------------------|-----------------------------------------------|----------------------------|---------------------------------|-----------------|-------------------------------|------------------------------------|
| Luxembourg                     | Eurogenerics<br>N.V./S.A.                     | Azithromycine Eg           | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension | oral use                           |
| Luxembourg                     | Eurogenerics<br>N.V./S.A.                     | Azithromycine Eg           | Azithromycin<br>Monohydrate     | 512mg           | film-coated tablet            | oral use                           |
| Luxembourg                     | Eurogenerics<br>N.V./S.A.                     | Azithromycine Eg           | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Luxembourg                     | Pfizer S.A.                                   | Zitromax                   | Azithromycin<br>Dihydrate       | 50.08mg         | powder for oral<br>suspension | oral use                           |
| Luxembourg                     | Pfizer S.A.                                   | Zitromax                   | Azithromycin<br>Dihydrate       | 628.84mg        | film-coated tablet            | oral use                           |
| Luxembourg                     | Pfizer S.A.                                   | Zitromax                   | Azithromycin<br>Dihydrate       | 524.03mg        | film-coated tablet            | oral use                           |
| Luxembourg                     | Pfizer S.A.                                   | Zitromax                   | Azithromycin<br>Dihydrate       | 262.01mg        | film-coated tablet            | oral use                           |
| Luxembourg                     | Ratiopharm GmbH                               | Azithromycin<br>Ratiopharm | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Luxembourg                     | Ratiopharm GmbH                               | Azithromycin<br>Ratiopharm | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Malta                          | Pfizer Hellas A.E.                            | Zithromax                  | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension | oral use                           |
| Malta                          | Pfizer Hellas A.E.                            | Zithromax                  | Azithromycin                    | 250mg           | capsule, hard                 | oral use                           |
| Malta                          | Piam Farmaceutici<br>SpA                      | Azitredil                  | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet            | oral use                           |
| Malta                          | Verisfield S.M.S.A                            | Zinfect                    | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |

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|--------------------------------|-----------------------------------------------|---------------------------|---------------------------------|-----------------|-----------------------------------------------------|------------------------------------|
| Netherlands                    | Aurobindo Pharma B.V.                         | Azitromycine<br>Aurobindo | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Aurobindo Pharma B.V.                         | Azitromycine<br>Aurobindo | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Centrafarm B.V.                               | Azitromycine Cf           | Azithromycin<br>Monohydrate     | 204.8mg/5ml     | powder for oral<br>suspension                       | oral use                           |
| Netherlands                    | Centrafarm B.V.                               | Azitromycine Cf           | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Centrafarm B.V.                               | Azitromycine Cf           | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Dr. Friedrich Eberth<br>Arzneimittel GmbH     | Azitromycine<br>Eberth    | Azithromycin                    | 1mg/ml          | powder for concentrate<br>for solution for infusion | intravenous use                    |
| Netherlands                    | Jubilant<br>Pharmaceuticals NV                | Azitromycine<br>Jubilant  | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Jubilant<br>Pharmaceuticals NV                | Azitromycine<br>Jubilant  | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Mylan<br>Pharmaceuticals<br>Limited           | Azitromycine Mylan        | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Mylan<br>Pharmaceuticals<br>Limited           | Azitromycine Mylan        | Azithromycin<br>Monohydrate     | 20mg/ml         | powder for oral<br>suspension                       | oral use                           |
| Netherlands                    | Mylan<br>Pharmaceuticals<br>Limited           | Azitromycine Mylan        | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Pfizer B.V.                                   | Zithromax                 | Anhydrous<br>Azithromycin       | 500mg           | film-coated tablet                                  | oral use                           |

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|--------------------------------|-----------------------------------------------|-----------------------------|---------------------------------|-----------------|-----------------------------------------------------|------------------------------------|
| Netherlands                    | Pfizer B.V.                                   | Zithromax                   | Anhydrous<br>Azithromycin       | 200mg/5ml       | powder for oral<br>suspension                       | oral use                           |
| Netherlands                    | Pfizer B.V.                                   | Zithromax                   | Anhydrous<br>Azithromycin       | 250mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Ratiopharm GmbH                               | Azithromycine<br>Ratiopharm | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension                       | oral use                           |
| Netherlands                    | Ratiopharm GmbH                               | Azitromycine<br>Ratiopharm  | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Ratiopharm GmbH                               | Azithromycine<br>Ratiopharm | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Sandoz B.V.                                   | Azitromycine<br>Sandoz B.V. | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension                       | oral use                           |
| Netherlands                    | Sandoz B.V.                                   | Azitromycine<br>Sandoz      | Azithromycin                    | 100mg/5ml       | powder for oral<br>suspension                       | oral use                           |
| Netherlands                    | Sandoz B.V.                                   | Azitromycine<br>Sandoz      | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Sandoz B.V.                                   | Azitromycine<br>Sandoz      | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Teva Nederland<br>B.V.                        | Azitromycine Teva           | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension                       | oral use                           |
| Netherlands                    | Teva Nederland<br>B.V.                        | Azithromycine Teva          | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Netherlands                    | Teva Nederland<br>B.V.                        | Azithromycine Teva          | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Norway                         | Macure Pharma ApS                             | Amzolynic                   | Azithromycin                    | 500mg           | powder for concentrate<br>for solution for infusion | intravenous use                    |

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|--------------------------------|---------------------------------------------------------|---------------------------|---------------------------------|-----------------|---------------------------------|------------------------------------|
| Norway                         | Pfizer AS                                               | Azitromax                 | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension   | oral use                           |
| Norway                         | Pfizer AS                                               | Azitromax                 | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Poland                         | Adamed Pharma<br>S.A.                                   | Azycyna                   | Azithromycin                    | 200mg/5ml       | granules for oral<br>suspension | oral use                           |
| Poland                         | Adamed Pharma<br>S.A.                                   | Azycyna                   | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Poland                         | Adamed Pharma<br>S.A.                                   | Azycyna                   | Azithromycin                    | 250mg           | film-coated tablet              | oral use                           |
| Poland                         | Artespharm Sp. Z<br>O.O.                                | Abiazyt                   | Azithromycin<br>Dihydrate       | 524.1mg         | coated tablet                   | oral use                           |
| Poland                         | Aurovitas Pharma<br>Polska Sp. Z O.O                    | Azithromycin<br>Aurovitas | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Poland                         | Aurovitas Pharma<br>Polska Sp. Z O.O                    | Azithromycin<br>Aurovitas | Azithromycin                    | 250mg           | film-coated tablet              | oral use                           |
| Poland                         | Bausch Health<br>Ireland Limited                        | Macromax                  | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Poland                         | Krka, d.d., Novo<br>Mesto                               | Azithromycin Krka         | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Poland                         | Krka, d.d., Novo<br>Mesto                               | Azithromycin Krka         | Azithromycin                    | 250mg           | film-coated tablet              | oral use                           |
| Poland                         | Krka, d.d., Novo<br>Mesto                               | Azibiot                   | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Poland                         | Przedsiębiorstwo<br>Farmaceutyczne<br>Lek-Am Sp. Z O.O. | Nobaxin                   | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |



| <b>Member State<br/>EU/EEA</b> | <b>Marketing<br/>authorisation<br/>holder</b>                           | <b>Product name</b>      | <b>INN/Active<br/>substance</b> | <b>Strength</b> | <b>Pharmaceutical form</b>    | <b>Route of<br/>administration</b> |
|--------------------------------|-------------------------------------------------------------------------|--------------------------|---------------------------------|-----------------|-------------------------------|------------------------------------|
| Poland                         | Sandoz GmbH                                                             | Azitrolek                | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension | oral use                           |
| Poland                         | Sandoz GmbH                                                             | Azitrolek                | Azithromycin                    | 100mg/5ml       | powder for oral<br>suspension | oral use                           |
| Poland                         | Sandoz GmbH                                                             | Azitrolek                | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Poland                         | Sandoz GmbH                                                             | Azitrolek                | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Poland                         | Sia, Zim<br>Laboratories Limited                                        | Azithromycin Zim         | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Poland                         | Synoptis Pharma Sp<br>Z O O                                             | Azithromycin<br>Genoptim | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Poland                         | Tarchomińskie<br>Zakłady<br>Farmaceutyczne<br>"polfa" Spółka<br>Akcyjna | Azimycin                 | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Poland                         | Tarchomińskie<br>Zakłady<br>Farmaceutyczne<br>"polfa" Spółka<br>Akcyjna | Azimycin                 | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension | oral use                           |
| Poland                         | Tarchomińskie<br>Zakłady<br>Farmaceutyczne<br>"polfa" Spółka<br>Akcyjna | Azimycin                 | Azithromycin                    | 100mg/5ml       | powder for oral<br>suspension | oral use                           |

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|--------------------------------|-------------------------------------------------------------------------|---------------------|---------------------------------|-----------------|-------------------------------|------------------------------------|
| Poland                         | Tarchomińskie<br>Zakłady<br>Farmaceutyczne<br>"polfa" Spółka<br>Akcyjna | Azimycin            | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Poland                         | Tarchomińskie<br>Zakłady<br>Farmaceutyczne<br>"polfa" Spółka<br>Akcyjna | Azimycin            | Azithromycin                    | 125mg           | film-coated tablet            | oral use                           |
| Poland                         | Teva B.V                                                                | Bactrazol           | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Poland                         | Teva<br>Pharmaceuticals<br>Polska Sp. Z O.O.                            | Sumamed             | Azithromycin                    | 1000mg          | dispersible tablet            | oral use                           |
| Poland                         | Teva<br>Pharmaceuticals<br>Polska Sp. Z O.O.                            | Sumamed             | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Poland                         | Teva<br>Pharmaceuticals<br>Polska Sp. Z O.O.                            | Sumamed Forte       | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension | oral use                           |
| Poland                         | Teva<br>Pharmaceuticals<br>Polska Sp. Z O.O.                            | Sumamed             | Azithromycin                    | 100mg/5ml       | powder for oral<br>suspension | oral use                           |
| Poland                         | Teva<br>Pharmaceuticals<br>Polska Sp. Z O.O.                            | Sumamed             | Azithromycin                    | 125mg           | film-coated tablet            | oral use                           |

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|--------------------------------|-----------------------------------------------|--------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Poland                         | Teva<br>Pharmaceuticals<br>Polska Sp. Z O.O.  | Sumamed                  | Azithromycin                    | 500mg           | dispersible tablet                  | oral use                           |
| Poland                         | Teva<br>Pharmaceuticals<br>Polska Sp. Z O.O.  | Sumamed                  | Azithromycin                    | 250mg           | dispersible tablet                  | oral use                           |
| Poland                         | Teva<br>Pharmaceuticals<br>Polska Sp. Z O.O.  | Azithromycin Teva        | Azithromycin                    | 500mg           | dispersible tablet                  | oral use                           |
| Poland                         | Teva<br>Pharmaceuticals<br>Polska Sp. Z O.O.  | Azithromycin Teva        | Azithromycin                    | 250mg           | dispersible tablet                  | oral use                           |
| Poland                         | Teva<br>Pharmaceuticals<br>Polska Sp. Z O.O.  | Sumamed                  | Azithromycin                    | 250mg           | capsule, hard                       | oral use                           |
| Poland                         | Zentiva, K.S.                                 | Azitrox                  | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Altan<br>Pharmaceuticals<br>S.A.              | Azitromicina Altan       | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion | intravenous use                    |
| Portugal                       | Alter S.A.                                    | Azitromicina Alter       | Azithromycin<br>Dihydrate       | 524.04mg        | coated tablet                       | oral use                           |
| Portugal                       | Alter S.A.                                    | Azitromicina Alter       | Azithromycin                    | 500mg           | coated tablet                       | oral use                           |
| Portugal                       | Baldacci - Portugal,<br>S.A.                  | Azitromicina<br>Baldacci | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Portugal                       | Baldacci - Portugal,<br>S.A.                  | Azitromicina<br>Baldacci | Azithromycin<br>Dihydrate       | 524mg           | film-coated tablet                  | oral use                           |

| <b>Member State<br/>EU/EEA</b> | <b>Marketing<br/>authorisation<br/>holder</b>                     | <b>Product name</b>                                            | <b>INN/Active<br/>substance</b> | <b>Strength</b> | <b>Pharmaceutical form</b>          | <b>Route of<br/>administration</b> |
|--------------------------------|-------------------------------------------------------------------|----------------------------------------------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Portugal                       | Biofarmoz-<br>Sociedade Técnico<br>Medicinal,<br>Unipessoal, Lda. | Azitromicina<br>Biofarmoz                                      | Azithromycin                    | 500mg           | powder for solution for<br>infusion | intravenous use                    |
| Portugal                       | Bluepharma<br>Genéricos -<br>Comércio De<br>Medicamentos, S.A.    | Azitromicina<br>Bluepharma                                     | Azithromycin                    | 500mg           | coated tablet                       | oral use                           |
| Portugal                       | Bluepharma<br>Indústria<br>Farmacêutica S.A.                      | Bluesar                                                        | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Bluepharma<br>Indústria<br>Farmacêutica S.A.                      | Bloza                                                          | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Bluepharma<br>Indústria<br>Farmacêutica S.A.                      | Bloza                                                          | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Bluepharma<br>Indústria<br>Farmacêutica S.A.                      | Azitromicina Oara<br>Bluepharma –<br>Indústria<br>Farmacêutica | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Ciclum Farma<br>Unipessoal Lda.                                   | Azitromicina Ciclum                                            | Azithromycin<br>Dihydrate       | 524mg           | coated tablet                       | oral use                           |
| Portugal                       | Faes Farma<br>Portugal, S.A.                                      | Azitromicina Vitória                                           | Azithromycin<br>Dihydrate       | 524mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Farmoz - Sociedade<br>Técnico Medicinal,<br>S.A.                  | Azitromicina<br>Farmoz                                         | Azithromycin                    | 500mg           | coated tablet                       | oral use                           |

| <b>Member State<br/>EU/EEA</b> | <b>Marketing<br/>authorisation<br/>holder</b>    | <b>Product name</b>       | <b>INN/Active<br/>substance</b> | <b>Strength</b> | <b>Pharmaceutical form</b>          | <b>Route of<br/>administration</b> |
|--------------------------------|--------------------------------------------------|---------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Portugal                       | Farmoz - Sociedade<br>Técnico Medicinal,<br>S.A. | Azitromicina<br>Farmoz    | Azithromycin<br>Dihydrate       | 524.03mg        | powder for solution for<br>infusion | intravenous use                    |
| Portugal                       | Fresenius Kabi<br>Pharma Portugal,<br>Lda.       | Azitromicina Kabi         | Azithromycin<br>Dihydrate       | 524.1mg         | powder for solution for<br>infusion | intravenous use                    |
| Portugal                       | Generis<br>Farmacêutica, S.A.                    | Azitromicina<br>Generis   | Azithromycin<br>Dihydrate       | 41.924mg/ml     | powder for oral<br>suspension       | oral use                           |
| Portugal                       | Generis<br>Farmacêutica, S.A.                    | Azitromicina<br>Aurovitas | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Generis<br>Farmacêutica, S.A.                    | Azitromicina<br>Aurobindo | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Generis<br>Farmacêutica, S.A.                    | Azitromicina<br>Labesfal  | Azithromycin<br>Dihydrate       | 524mg           | coated tablet                       | oral use                           |
| Portugal                       | Generis<br>Farmacêutica, S.A.                    | Azitromicina<br>Generis   | Azithromycin<br>Dihydrate       | 524mg           | coated tablet                       | oral use                           |
| Portugal                       | Generis<br>Farmacêutica, S.A.                    | Azitromicina<br>Aurovitas | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Germed<br>Farmacêutica, Lda.                     | Ziger                     | Azithromycin<br>Dihydrate       | 524.05mg        | film-coated tablet                  | oral use                           |
| Portugal                       | Germed<br>Farmacêutica, Lda.                     | Azitromicina<br>Germed    | Azithromycin<br>Dihydrate       | 524mg           | coated tablet                       | oral use                           |
| Portugal                       | Gp – Genéricos<br>Portugueses, Lda.              | Azitromicina Gp           | Azithromycin<br>Dihydrate       | 524mg           | coated tablet                       | oral use                           |
| Portugal                       | Gp – Genéricos<br>Portugueses, Lda.              | Azitromicina Gp           | Azithromycin                    | 524mg           | coated tablet                       | oral use                           |

| <b>Member State<br/>EU/EEA</b> | <b>Marketing<br/>authorisation<br/>holder</b>                 | <b>Product name</b>      | <b>INN/Active<br/>substance</b> | <b>Strength</b> | <b>Pharmaceutical form</b>          | <b>Route of<br/>administration</b> |
|--------------------------------|---------------------------------------------------------------|--------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Portugal                       | Jaba Recordati, S.A.                                          | Azitromicina Jaba        | Azithromycin                    | 500mg           | coated tablet                       | oral use                           |
| Portugal                       | Krka Farmacêutica,<br>Unipessoal Lda.                         | Azitromicina Krka        | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Mylan, Lda                                                    | Azitromicina Mylan       | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Laboratórios Atral,<br>S.A.                                   | Azitromicina Atral       | Azithromycin                    | 500mg           | coated tablet                       | oral use                           |
| Portugal                       | Laboratórios<br>Azevedos -<br>Indústria<br>Farmacêutica, S.A. | Azitromicina<br>Azevedos | Azithromycin<br>Dihydrate       | 524.01mg        | coated tablet                       | oral use                           |
| Portugal                       | Laboratórios<br>Azevedos -<br>Indústria<br>Farmacêutica, S.A. | Azitromicina<br>Azevedos | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion | intravenous use                    |
| Portugal                       | Laboratórios Basi –<br>Indústria<br>Farmacêutica, S.A.        | Azitromicina Basi        | Azithromycin<br>Dihydrate       | 524mg           | coated tablet                       | oral use                           |
| Portugal                       | Laboratórios Basi –<br>Indústria<br>Farmacêutica, S.A.        | Azitromicina Basi        | Azithromycin<br>Dihydrate       | 524mg           | powder for solution for<br>infusion | intravenous use                    |
| Portugal                       | Laboratórios Basi –<br>Indústria<br>Farmacêutica, S.A.        | Azitromicina<br>Clintex  | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Portugal                       | Laboratórios Pfizer<br>Lda.                                   | Zithromax                | Azithromycin<br>Dihydrate       | 209.64mg/5ml    | powder for oral<br>suspension       | oral use                           |

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|--------------------------------|------------------------------------------------------|----------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Portugal                       | Laboratórios Pfizer<br>Lda.                          | Zithromax                  | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet                  | oral use                           |
| Portugal                       | Laboratórios Pfizer<br>Lda.                          | Zithromax IV               | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion | intravenous use                    |
| Portugal                       | Mylan, Lda                                           | Azitromicina Mylan         | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Mylan, Lda                                           | Azitromicina Mylan         | Azithromycin<br>Monohydrate     | 40.96mg/ml      | powder for oral<br>suspension       | oral use                           |
| Portugal                       | Pentafarma -<br>Sociedade Tecnico-<br>Medicinal S.A. | Azitromicina<br>Pentafarma | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Portugal                       | Pentafarma -<br>Sociedade Tecnico-<br>Medicinal S.A. | Azitrix                    | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Portugal                       | Pentafarma -<br>Sociedade Tecnico-<br>Medicinal S.A. | Azitromicina<br>Pentafarma | Azithromycin<br>Dihydrate       | 524mg           | coated tablet                       | oral use                           |
| Portugal                       | Pentafarma -<br>Sociedade Tecnico-<br>Medicinal S.A. | Azitromicina<br>Pentafarma | Azithromycin                    | 500mg           | coated tablet                       | oral use                           |
| Portugal                       | Pentafarma -<br>Sociedade Tecnico-<br>Medicinal S.A. | Azitromicina Azitrix       | Azithromycin                    | 500mg           | coated tablet                       | oral use                           |
| Portugal                       | Pentafarma -<br>Sociedade Tecnico-<br>Medicinal S.A. | Azitromicina Almus         | Azithromycin                    | 500mg           | coated tablet                       | oral use                           |

| <b>Member State<br/>EU/EEA</b> | <b>Marketing<br/>authorisation<br/>holder</b>                                        | <b>Product name</b>        | <b>INN/Active<br/>substance</b> | <b>Strength</b> | <b>Pharmaceutical form</b>          | <b>Route of<br/>administration</b> |
|--------------------------------|--------------------------------------------------------------------------------------|----------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Portugal                       | Pentafarma -<br>Sociedade Tecnico-<br>Medicinal S.A.                                 | Azitromicina Legin         | Azithromycin                    | 500mg           | powder for solution for<br>infusion | intravenous use                    |
| Portugal                       | Pharmakern<br>Portugal – Produtos<br>Farmacêuticos,<br>Sociedade<br>Unipessoal, Lda. | Azitromicina<br>Pharmakern | Azithromycin<br>Dihydrate       | 524mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Sandoz<br>Farmacêutica Lda.                                                          | Azitromicina<br>Sandoz     | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Sia, Zim<br>Laboratories Limited                                                     | Azitromicina Zim           | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Sidefarma -<br>Sociedade Industrial<br>De Expansão<br>Farmacêutica, S.A.             | Zitrozina                  | Azithromycin<br>Dihydrate       | 524.01mg        | coated tablet                       | oral use                           |
| Portugal                       | Teva B.V                                                                             | Sumamed                    | Azithromycin                    | 1000mg          | dispersible tablet                  | oral use                           |
| Portugal                       | Teva B.V                                                                             | Sumamed                    | Azithromycin                    | 500mg           | dispersible tablet                  | oral use                           |
| Portugal                       | Teva Pharma –<br>Produtos<br>Farmacêuticos Lda                                       | Azitromicina Teva          | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Portugal                       | Teva Pharma –<br>Produtos<br>Farmacêuticos Lda                                       | Azitromicina Teva          | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Portugal                       | Towa<br>Pharmaceutical S.A.                                                          | Azitromicina Tolife        | Azithromycin<br>Dihydrate       | 524mg           | coated tablet                       | oral use                           |



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|--------------------------------|-----------------------------------------------|--------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Portugal                       | Zentiva Portugal,<br>Lda                      | Azitromicina<br>Zentiva  | Azithromycin<br>Dihydrate       | 524.01mg        | film-coated tablet                  | oral use                           |
| Romania                        | Arena Group S.A                               | Azitromicină Arena       | Azithromycin<br>Dihydrate       | 524mg           | film-coated tablet                  | oral use                           |
| Romania                        | Krka, d.d., Novo<br>Mesto                     | Azibiot                  | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension       | oral use                           |
| Romania                        | Krka, d.d., Novo<br>Mesto                     | Azibiot                  | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Romania                        | S.C. Rompharm<br>Company S.r.l.               | Azitromicină<br>Rompharm | Azithromycin                    | 500mg           | powder for solution for<br>infusion | intravenous use                    |
| Romania                        | S.C. Sandoz S.r.l.                            | Azitromicină<br>Sandoz   | Azithromycin<br>Monohydrate     | 209.6mg/5ml     | powder for oral<br>suspension       | oral use                           |
| Romania                        | S.C. Sandoz S.r.l.                            | Azitromicină<br>Sandoz   | Azithromycin<br>Dihydrate       | 209.6mg/5ml     | powder for oral<br>suspension       | oral use                           |
| Romania                        | S.C. Sandoz S.r.l.                            | Azitromicină<br>Sandoz   | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Romania                        | S.C. Sandoz S.r.l.                            | Azitromicina<br>Sandoz   | Azithromycin<br>Dihydrate       | 209.6mg/5ml     | powder for oral<br>suspension       | oral use                           |
| Romania                        | S.C. Sandoz S.r.l.                            | Azitromicina<br>Sandoz   | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Romania                        | S.C. Sandoz S.r.l.                            | Azitromicină<br>Sandoz   | Azithromycin<br>Dihydrate       | 104.8mg/5ml     | powder for oral<br>suspension       | oral use                           |
| Romania                        | S.C. Sandoz S.r.l.                            | Azitromicina<br>Sandoz   | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| Romania                        | Terapia S.A.                                  | Azitromicină<br>Terapia  | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |

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|--------------------------------|-----------------------------------------------|------------------------|---------------------------------|-----------------|-------------------------------|------------------------------------|
| Romania                        | Teva B.V                                      | Sumamed Forte          | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension | oral use                           |
| Romania                        | Teva B.V                                      | Sumamed                | Azithromycin<br>Dihydrate       | 524.109mg       | film-coated tablet            | oral use                           |
| Romania                        | Teva B.V                                      | Sumamed                | Azithromycin<br>Dihydrate       | 131.027mg       | film-coated tablet            | oral use                           |
| Romania                        | Teva B.V                                      | Sumamed                | Azithromycin                    | 250mg           | capsule, hard                 | oral use                           |
| Romania                        | Zentiva S.A.                                  | Azitrox                | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension | oral use                           |
| Romania                        | Zentiva, K.S.                                 | Azitrox                | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Slovakia                       | Krka, d.d., Novo<br>Mesto                     | Azibiot Neo            | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension | oral use                           |
| Slovakia                       | Krka, d.d., Novo<br>Mesto                     | Azibiot Neo            | Azithromycin                    | 20mg/ml         | powder for oral<br>suspension | oral use                           |
| Slovakia                       | Krka, d.d., Novo<br>Mesto                     | Azibiot Neo            | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Slovakia                       | Krka, d.d., Novo<br>Mesto                     | Azibiot Neo            | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Slovakia                       | Krka, d.d., Novo<br>Mesto                     | Azibiot                | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Slovakia                       | Mylan Ireland<br>Limited                      | Azitromycin Mylan      | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Slovakia                       | Sandoz GmbH                                   | Azithromycin<br>Sandoz | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |

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|--------------------------------|-----------------------------------------------|------------------------|---------------------------------|-----------------|-------------------------------|------------------------------------|
| Slovakia                       | Sandoz GmbH                                   | Azithromycin<br>Sandoz | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| Slovakia                       | Sandoz<br>Pharmaceuticals<br>d.d.             | Azithromycin<br>Sandoz | Azithromycin<br>Dihydrate       | 209.6mg/5ml     | powder for oral<br>suspension | oral use                           |
| Slovakia                       | Teva<br>Pharmaceuticals<br>Slovakia S.R.O     | Sumamed                | Azithromycin                    | 125mg           | film-coated tablet            | oral use                           |
| Slovakia                       | Teva<br>Pharmaceuticals<br>Slovakia S.R.O     | Sumamed Forte          | Azithromycin                    | 200mg/5ml       | powder for syrup              | oral use                           |
| Slovakia                       | Teva<br>Pharmaceuticals<br>Slovakia S.R.O     | Sumamed                | Azithromycin                    | 100mg/5ml       | powder for oral<br>suspension | oral use                           |
| Slovakia                       | Teva<br>Pharmaceuticals<br>Slovakia S.R.O     | Sumamed                | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Slovakia                       | Teva<br>Pharmaceuticals<br>Slovakia S.R.O     | Sumamed                | Azithromycin                    | 250mg           | capsule, hard                 | oral use                           |
| Slovakia                       | Zentiva, K.S.                                 | Azitrox                | Azithromycin<br>Dihydrate       | 262mg           | film-coated tablet            | oral use                           |
| Slovakia                       | Zentiva, K.S.                                 | Azitrox                | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| Slovenia                       | Krka, d.d., Novo<br>Mesto                     | Azitromicin Krka       | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension | oral use                           |
| Slovenia                       | Krka, d.d., Novo<br>Mesto                     | Azitromicin Krka       | Azithromycin                    | 20mg/ml         | powder for oral<br>suspension | oral use                           |

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|--------------------------------|-----------------------------------------------|---------------------|---------------------------------|-----------------|----------------------------------|------------------------------------|
| Slovenia                       | Krka, d.d., Novo Mesto                        | Azitromicin Krka    | Azithromycin                    | 500mg           | film-coated tablet               | oral use                           |
| Slovenia                       | Krka, d.d., Novo Mesto                        | Azitromicin Krka    | Azithromycin                    | 250mg           | film-coated tablet               | oral use                           |
| Slovenia                       | Krka, d.d., Novo Mesto                        | Azibiot             | Azithromycin                    | 500mg           | film-coated tablet               | oral use                           |
| Slovenia                       | Pliva Ljubljana d.o.o.;                       | Sumamed             | Azithromycin Dihydrate          | 524.1mg         | powder for solution for infusion | intravenous use                    |
| Slovenia                       | Pliva Ljubljana d.o.o.;                       | Sumamed             | Azithromycin                    | 500mg           | film-coated tablet               | oral use                           |
| Slovenia                       | Pliva Ljubljana d.o.o.;                       | Sumamed Za Otroke   | Azithromycin                    | 20mg/ml         | powder for oral suspension       | oral use                           |
| Slovenia                       | Pliva Ljubljana d.o.o.;                       | Sumamed             | Azithromycin                    | 40mg/ml         | powder for oral suspension       | oral use                           |
| Slovenia                       | Pliva Ljubljana d.o.o.;                       | Sumamed             | Azithromycin Dihydrate          | 131.027mg       | film-coated tablet               | oral use                           |
| Slovenia                       | Pliva Ljubljana d.o.o.;                       | Sumamed             | Azithromycin                    | 250mg           | capsule, hard                    | oral use                           |
| Spain                          | Almus Farmaceutica S.A.                       | Azitromicina Almus  | Azithromycin Dihydrate          | 524.05mg        | film-coated tablet               | oral use                           |
| Spain                          | Altan Pharmaceuticals S.A.                    | Azitromicina Altan  | Azithromycin                    | 100mg/ml        | powder for solution for infusion | intravenous use                    |
| Spain                          | Apotex Europe B.V.                            | Azitromicina Apotex | Azithromycin                    | 500mg           | film-coated tablet               | oral use                           |
| Spain                          | Arafarma Group, S.A                           | Aratro              | Azithromycin                    | 500mg           | powder for oral suspension       | oral use                           |

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|--------------------------------|--------------------------------------------------|----------------------------|---------------------------------|-----------------|-----------------------------------------|------------------------------------|
| Spain                          | Arafarma Group,<br>S.A                           | Aratro                     | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension           | oral use                           |
| Spain                          | Arafarma Group,<br>S.A                           | Aratro                     | Azithromycin                    | 500mg           | film-coated tablet                      | oral use                           |
| Spain                          | Aristo Pharma<br>GmbH (Art 57)                   | Azitromicina<br>Aristogen  | Azithromycin                    | 500mg           | film-coated tablet                      | oral use                           |
| Spain                          | Aristo Pharma<br>Iberia, S.L.                    | Azitromicina Aristo        | Azithromycin                    | 500mg           | film-coated tablet                      | oral use                           |
| Spain                          | Aurovitas<br>Spain,s.A.U.                        | Azitromicina<br>Aurovitas  | Azithromycin                    | 500mg           | film-coated tablet                      | oral use                           |
| Spain                          | Auxilto Healthcare<br>GmbH                       | Azitromicina Auxil         | Azithromycin                    | 500mg           | film-coated tablet                      | oral use                           |
| Spain                          | Bluepharma<br>Indústria<br>Farmacêutica S.A.     | Azitromicina<br>Bluepharma | Azithromycin<br>Dihydrate       | 524mg           | film-coated tablet                      | oral use                           |
| Spain                          | Dermogen Farma,<br>S.A.                          | Azitromicina Benel         | Azithromycin                    | 250mg           | powder for oral<br>suspension in sachet | oral use                           |
| Spain                          | Dermogen Farma,<br>S.A.                          | Azitromicina Benel         | Azithromycin                    | 500mg           | powder for oral<br>suspension           | oral use                           |
| Spain                          | Dermogen Farma,<br>S.A.                          | Azitromicina Benel         | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension           | oral use                           |
| Spain                          | Dermogen Farma,<br>S.A.                          | Azitromicina Benel         | Azithromycin                    | 500mg           | film-coated tablet                      | oral use                           |
| Spain                          | Industria Química Y<br>Farmacéutica Vir,<br>S.A. | Azitromicina Vir           | Azithromycin                    | 500mg           | film-coated tablet                      | oral use                           |

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|--------------------------------|-----------------------------------------------|-----------------------------|---------------------------------|-----------------|---------------------------------|------------------------------------|
| Spain                          | Kern Pharma, S.L.                             | Azitromicina Kern<br>Pharma | Azithromycin                    | 500mg           | powder for oral<br>suspension   | oral use                           |
| Spain                          | Kern Pharma, S.L.                             | Azitromicina Kern<br>Pharma | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension   | oral use                           |
| Spain                          | Kern Pharma, S.L.                             | Azitromicina Kern<br>Pharma | Azithromycin                    | 250mg           | powder for oral<br>suspension   | oral use                           |
| Spain                          | Kern Pharma, S.L.                             | Azitromicina Kern<br>Pharma | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Spain                          | Korhispana, S.L.                              | Azitromicina<br>Korhispana  | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Spain                          | Krka, d.d., Novo<br>Mesto                     | Azitromicina Krka           | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Spain                          | Krka, d.d., Novo<br>Mesto                     | Azitromicina Krka           | Azithromycin                    | 250mg           | film-coated tablet              | oral use                           |
| Spain                          | Laboratorio Stada,<br>S.L.                    | Azitromicina Stada          | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension   | oral use                           |
| Spain                          | Laboratorio Stada,<br>S.L.                    | Azitromicina Stada          | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Spain                          | Laboratorios Alter,<br>S.A.                   | Azitromicina Alter          | Azithromycin                    | 500mg           | granules for oral<br>suspension | oral use                           |
| Spain                          | Laboratorios Alter,<br>S.A.                   | Azitromicina Alter          | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Spain                          | Laboratorios Cinfa,<br>S.A.                   | Azitromicina Cinfa          | Azithromycin                    | 500mg           | powder for oral<br>suspension   | oral use                           |
| Spain                          | Laboratorios Cinfa,<br>S.A.                   | Azitromicina Cinfa          | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |

| <b>Member State<br/>EU/EEA</b> | <b>Marketing<br/>authorisation<br/>holder</b> | <b>Product name</b>      | <b>INN/Active<br/>substance</b> | <b>Strength</b> | <b>Pharmaceutical form</b>          | <b>Route of<br/>administration</b> |
|--------------------------------|-----------------------------------------------|--------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Spain                          | Laboratorios<br>Combix, S.L.U.                | Azitromicina<br>Combix   | Azithromycin<br>Dihydrate       | 524.05mg        | film-coated tablet                  | oral use                           |
| Spain                          | Laboratorios<br>Normon, S.A.                  | Azitromicina<br>Normon   | Azithromycin                    | 500mg           | powder for oral<br>suspension       | oral use                           |
| Spain                          | Laboratorios<br>Normon, S.A.                  | Azitromicina<br>Normon   | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Spain                          | Mabo-Farma, S.A                               | Azitromicina Mabo        | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Spain                          | Mylan<br>Pharmaceuticals<br>S.L.              | Azitromicina Mylan       | Azithromycin                    | 500mg           | powder for oral<br>suspension       | oral use                           |
| Spain                          | Neuraxpharm<br>Spain, S.L.U.                  | Azitromicina<br>Qualigen | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension       | oral use                           |
| Spain                          | Neuraxpharm<br>Spain, S.L.U.                  | Azitromicina<br>Qualigen | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Spain                          | Pfizer S.L.                                   | Zitromax                 | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion | intravenous use                    |
| Spain                          | Pfizer S.L.                                   | Zitromax                 | Azithromycin                    | 500mg           | powder for oral<br>suspension       | oral use                           |
| Spain                          | Pfizer S.L.                                   | Zitromax                 | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension       | oral use                           |
| Spain                          | Pfizer S.L.                                   | Zitromax                 | Azithromycin                    | 250mg           | powder for oral<br>suspension       | oral use                           |
| Spain                          | Pfizer S.L.                                   | Zitromax                 | Azithromycin                    | 1000mg          | powder for oral<br>suspension       | oral use                           |
| Spain                          | Pfizer S.L.                                   | Zitromax                 | Azithromycin                    | 250mg           | capsule, hard                       | oral use                           |

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|--------------------------------|-------------------------------------------------|--------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| Spain                          | Pfizer S.L.                                     | Zitromax                 | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Spain                          | Sandoz<br>Farmacéutica, S.A.                    | Azitromicina<br>Sandoz   | Azithromycin                    | 250mg           | powder for oral<br>suspension       | oral use                           |
| Spain                          | Sandoz<br>Farmacéutica, S.A.                    | Azitromicina<br>Sandoz   | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |
| Spain                          | Sandoz<br>Farmacéutica, S.A.                    | Azitromicina<br>Sandoz   | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Spain                          | Sandoz<br>Farmacéutica, S.A.                    | Azitromicina<br>Sandoz   | Azithromycin                    | 500mg           | powder for oral<br>suspension       | oral use                           |
| Spain                          | Sun Pharmaceutical<br>Industries Europe<br>B.V. | Azitromicina Sun         | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Spain                          | Tarbis Farma, S.L.                              | Azitromicina Tarbis      | Azithromycin                    | 500mg           | powder for oral<br>suspension       | oral use                           |
| Spain                          | Tarbis Farma, S.L.                              | Azitromicina Tarbis      | Azithromycin                    | 250mg           | powder for oral<br>suspension       | oral use                           |
| Spain                          | Tarbis Farma, S.L.                              | Azitromicina Tarbis      | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| Spain                          | Tarbis Farma, S.L.                              | Azitromicina Tarbis      | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension       | oral use                           |
| Spain                          | Tecnimed España<br>Ind. Fca., S.A.              | Azitromicina<br>Tecnigen | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion | intravenous use                    |
| Spain                          | Tecnimed España<br>Ind. Fca., S.A.              | Azitromicina<br>Tecnigen | Azithromycin<br>Dihydrate       | 524.05mg        | film-coated tablet                  | oral use                           |
| Spain                          | Teva Pharma<br>S.L.U.,                          | Azitromicina Ratio       | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension       | oral use                           |



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|--------------------------------|-----------------------------------------------|----------------------------|---------------------------------|-----------------|---------------------------------|------------------------------------|
| Spain                          | Teva Pharma<br>S.L.U.,                        | Azithromycina Teva         | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension   | oral use                           |
| Spain                          | Teva Pharma<br>S.L.U.,                        | Azitromicina Teva          | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Spain                          | Teva Pharma<br>S.L.U.,                        | Azitromicina Teva          | Azithromycin                    | 250mg           | film-coated tablet              | oral use                           |
| Spain                          | Teva Pharma<br>S.L.U.,                        | Azitromicina Ratio         | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Spain                          | Teva Pharma<br>S.L.U.,                        | Azitromicina Teva          | Azithromycin                    | 500mg           | dispersible tablet              | oral use                           |
| Spain                          | Teva Pharma<br>S.L.U.,                        | Azitromicina Teva          | Azithromycin                    | 250mg           | dispersible tablet              | oral use                           |
| Spain                          | Teva Pharma<br>S.L.U.,                        | Azitromicina<br>Ratiopharm | Azithromycin                    | 250mg           | dispersible tablet              | oral use                           |
| Spain                          | Teva Pharma<br>S.L.U.,                        | Azitromicina<br>Ratiopharm | Azithromycin                    | 500mg           | dispersible tablet              | oral use                           |
| Spain                          | Towa<br>Pharmaceutical S.A.                   | Azitromicina Pensa         | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |
| Spain                          | Towa<br>Pharmaceutical S.A.                   | Azitromicina Pensa         | Azithromycin                    | 500mg           | granules for oral<br>suspension | oral use                           |
| Spain                          | Viartis<br>Pharmaceuticals,<br>S.L.U.         | Azitromicina Viartis       | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension   | oral use                           |
| Spain                          | Viartis<br>Pharmaceuticals,<br>S.L.U.         | Azitromicina Viartis       | Azithromycin                    | 500mg           | film-coated tablet              | oral use                           |

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|--------------------------------|-----------------------------------------------|--------------------------|---------------------------------|-----------------|-----------------------------------------------------|------------------------------------|
| Sweden                         | Jubilant<br>Pharmaceuticals NV                | Azithromycin<br>Jubilant | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Sweden                         | Jubilant<br>Pharmaceuticals NV                | Azithromycin<br>Jubilant | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Sweden                         | Krka, d.d., Novo<br>Mesto                     | Azithromycin Krka        | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Sweden                         | Krka, d.d., Novo<br>Mesto                     | Azithromycin Krka        | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Sweden                         | Macure Pharma ApS                             | Amzolynic                | Azithromycin                    | 100mg/ml        | powder for concentrate<br>for solution for infusion | intravenous use                    |
| Sweden                         | Mylan AB                                      | Azithromycin Mylan       | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Sweden                         | Pfizer AB                                     | Azitromax                | Azithromycin                    | 1mg/ml          | powder for concentrate<br>for solution for infusion | intravenous use                    |
| Sweden                         | Pfizer AB                                     | Azitromax                | Azithromycin                    | 40mg/ml         | powder for oral<br>suspension                       | oral use                           |
| Sweden                         | Pfizer AB                                     | Azitromax                | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Sweden                         | Sandoz A/S                                    | Azithromycin<br>Sandoz   | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Sweden                         | Sandoz A/S                                    | Azithromycin<br>Sandoz   | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| Sweden                         | Stada Arzneimittel<br>AG                      | Azithromycin Stada       | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| Sweden                         | Stada Arzneimittel<br>AG                      | Azithromycin Stada       | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |

| <b>Member State<br/>EU/EEA</b>       | <b>Marketing<br/>authorisation<br/>holder</b> | <b>Product name</b>                            | <b>INN/Active<br/>substance</b> | <b>Strength</b> | <b>Pharmaceutical form</b>          | <b>Route of<br/>administration</b> |
|--------------------------------------|-----------------------------------------------|------------------------------------------------|---------------------------------|-----------------|-------------------------------------|------------------------------------|
| United Kingdom<br>(Northern Ireland) | Accord Healthcare<br>Limited                  | Clamelle                                       | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| United Kingdom<br>(Northern Ireland) | Accord-Uk Limited                             | Azithromycin<br>Accord-Uk                      | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| United Kingdom<br>(Northern Ireland) | Accord-Uk Limited                             | Azithromycin<br>Accord-Uk                      | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| United Kingdom<br>(Northern Ireland) | Morningside<br>Healthcare (Malta)<br>Limited  | Zedbac                                         | Azithromycin                    | 100mg/ml        | powder for solution for<br>infusion | intravenous use                    |
| United Kingdom<br>(Northern Ireland) | Crescent Pharma<br>Limited                    | Azithromycin<br>Crescent Pharma                | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| United Kingdom<br>(Northern Ireland) | Crescent Pharma<br>Limited                    | Azithromycin<br>Crescent Pharma                | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| United Kingdom<br>(Northern Ireland) | Crescent Pharma<br>Limited                    | Azithromycin<br>Crescent Pharma                | Azithromycin                    | 250mg           | capsule, hard                       | oral use                           |
| United Kingdom<br>(Northern Ireland) | Dawa Limited                                  | Azithromycin Dawa                              | Azithromycin                    | 250mg           | capsule, hard                       | oral use                           |
| United Kingdom<br>(Northern Ireland) | Generics [uk]<br>Limited                      | Azithromycin<br>Generics [uk]                  | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| United Kingdom<br>(Northern Ireland) | Generics [uk]<br>Limited                      | Azithromycin<br>Generics [uk]                  | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |
| United Kingdom<br>(Northern Ireland) | Jubilant<br>Pharmaceuticals NV                | Azithromycin<br>Jubilant<br>Pharmaceuticals NV | Azithromycin                    | 500mg           | film-coated tablet                  | oral use                           |
| United Kingdom<br>(Northern Ireland) | Jubilant<br>Pharmaceuticals NV                | Azithromycin<br>Jubilant<br>Pharmaceuticals NV | Azithromycin                    | 250mg           | film-coated tablet                  | oral use                           |

| <b>Member State<br/>EU/EEA</b>       | <b>Marketing<br/>authorisation<br/>holder</b> | <b>Product name</b>                         | <b>INN/Active<br/>substance</b> | <b>Strength</b> | <b>Pharmaceutical form</b>                          | <b>Route of<br/>administration</b> |
|--------------------------------------|-----------------------------------------------|---------------------------------------------|---------------------------------|-----------------|-----------------------------------------------------|------------------------------------|
| United Kingdom<br>(Northern Ireland) | Jubilant<br>Pharmaceuticals NV                | Azithromycin<br>Jubilant<br>Pharmaceuticals | Azithromycin                    | 250mg           | capsule, hard                                       | oral use                           |
| United Kingdom<br>(Northern Ireland) | Kensington Pharma<br>Ltd                      | Azithromycin<br>Kensington Pharma           | Azithromycin                    | 100mg/ml        | powder for concentrate<br>for solution for infusion | intravenous use                    |
| United Kingdom<br>(Northern Ireland) | Milpharm Limited                              | Azithromycin<br>Milpharm                    | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| United Kingdom<br>(Northern Ireland) | Milpharm Limited                              | Azithromycin<br>Milpharm                    | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| United Kingdom<br>(Northern Ireland) | Pfizer Limited                                | Zithromax                                   | Azithromycin<br>Dihydrate       | 209.6mg/5ml     | powder for oral<br>suspension                       | oral use                           |
| United Kingdom<br>(Northern Ireland) | Pfizer Limited                                | Zithromax                                   | Azithromycin<br>Dihydrate       | 262.05mg        | capsule, hard                                       | oral use                           |
| United Kingdom<br>(Northern Ireland) | Sandoz Ltd                                    | Azithromycin<br>Sandoz                      | Azithromycin<br>Monohydrate     | 204.8mg/5ml     | powder for oral<br>suspension                       | oral use                           |
| United Kingdom<br>(Northern Ireland) | Sandoz Ltd                                    | Azithromycin<br>Sandoz Ltd                  | Azithromycin                    | 250mg           | film-coated tablet                                  | oral use                           |
| United Kingdom<br>(Northern Ireland) | Sandoz Ltd                                    | Azithromycin<br>Sandoz                      | Azithromycin                    | 500mg           | film-coated tablet                                  | oral use                           |
| United Kingdom<br>(Northern Ireland) | Strandhaven<br>Limited T/A Somex<br>Pharma    | Azithromycin                                | Azithromycin<br>Dihydrate       | 524.1mg         | film-coated tablet                                  | oral use                           |
| United Kingdom<br>(Northern Ireland) | Strandhaven<br>Limited T/A Somex<br>Pharma    | Azithromycin                                | Azithromycin<br>Dihydrate       | 262.05mg        | film-coated tablet                                  | oral use                           |

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|--------------------------------------|-----------------------------------------------|-----------------------------|---------------------------------|-----------------|-------------------------------|------------------------------------|
| United Kingdom<br>(Northern Ireland) | Strandhaven<br>Limited T/A Somex<br>Pharma    | Azithromycin<br>Strandhaven | Azithromycin                    | 250mg           | capsule, hard                 | oral use                           |
| United Kingdom<br>(Northern Ireland) | Teva Uk Limited                               | Azithromycin Teva<br>Uk     | Azithromycin                    | 200mg/5ml       | powder for oral<br>suspension | oral use                           |
| United Kingdom<br>(Northern Ireland) | Teva Uk Limited                               | Azithromycin Teva<br>Uk     | Azithromycin                    | 500mg           | film-coated tablet            | oral use                           |
| United Kingdom<br>(Northern Ireland) | Teva Uk Limited                               | Azithromycin Teva<br>Uk     | Azithromycin                    | 250mg           | film-coated tablet            | oral use                           |
| United Kingdom<br>(Northern Ireland) | Teva Uk Limited                               | Azithromycin Teva<br>Uk     | Azithromycin                    | 250mg           | capsule, hard                 | oral use                           |