



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

30 November 2017  
EMA/817628/2017  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: Omeprazole

Procedure no.: PSUSA/00002215/201704

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| Product Name<br>(in authorisation country)                             | MRP/DCP Authorisation<br>Number | National Authorisation<br>Number | MAH of product in the<br>Member State | Member State where<br>product is authorised |
|--|---------------------------------|----------------------------------|---------------------------------------|---|
| Omeprazol NLP Health 40 mg<br>cápsulas duras gastrorresistentes        | not available                   | 81270                            | NEWLINE PHARMA S.L.                   | ES  |
| Omeprazol Hetero 40 mg<br>cápsulas duras gastrorresistentes            | PT/H/1213/003                   | 80247                            | HETERO EUROPE S.L.                    | ES  |
| Omeprazol PHARMAKERN 40 mg<br>cápsulas duras gastrorresistentes        | not available                   | 78932                            | KERN PHARMA, S.L.                     | ES  |
| Omezol STADA 20 mg<br>magensaftresistente Tabletten                    | DE/H/0321/001                   | 50198.00.00                      | STADA ARZNEIMITTEL AG                 | DE  |
| Losamel 20 mg gastro-resistant<br>tablets                              | DE/H/0321/001                   | PA0126/115/001                   | CLONMEL HEALTHCARE LTD.               | IE  |
| OMPRANYT 20 mg cápsulas duras<br>gastrorresistentes                    | not available                   | 59.807                           | LABORATORIOS BIAL, S.A.               | ES  |
| OMEPRAZOL NORMON 40 mg<br>CAPSULAS DURAS<br>GASTRORRESISTENTES         | not available                   | 72.532                           | LABORATORIOS NORMON,<br>S.A.          | ES  |
| Gastrimut 20 mg cápsulas duras<br>gastrorresistentes                   | not available                   | 59.842                           | LABORATORIOS NORMON,<br>S.A.          | ES  |
| Omeprazol NORMON 10 mg<br>Cápsulas duras gastrorresistentes            | not available                   | 69233                            | LABORATORIOS NORMON,<br>S.A.          | ES  |
| Omeprazol Gobens 10 mg<br>cápsulas duras gastrorresistentes            | not available                   | 81391                            | LABORATORIOS NORMON,<br>S.A.          | ES  |
| Omeprazol Gobens 40 mg<br>cápsulas duras gastrorresistentes            | not available                   | 81393                            | LABORATORIOS NORMON,<br>S.A.          | ES  |
| Omeprazol NewLine Pharma 40<br>mg cápsulas duras<br>gastrorresistentes | not available                   | 80997                            | NEWLINE PHARMA S.L.                   | ES  |
| Miol 20 mg cápsulas duras<br>gastrorresistentes                        | not available                   | 58.696                           | FERRER INTERNACIONAL, S.A.            | ES  |

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| OMEZOLAN 10 mg capsulas duras<br>gastro-resistentes  | not available                   | 3272598                          | ARISTO PHARMA IBERIA, S.L.            | PT  |
| OMEZOLAN 10 mg capsulas duras<br>gastro-resistentes  | not available                   | 3272697                          | ARISTO PHARMA IBERIA, S.L.            | PT  |
| OMEZOLAN 10 mg capsulas duras<br>gastro-resistentes  | not available                   | 3272796                          | ARISTO PHARMA IBERIA, S.L.            | PT  |
| Omezolan 40 mg capsulas duras<br>gastro-resistentes  | not available                   | 3272093                          | ARISTO PHARMA IBERIA, S.L.            | PT  |
| Omezolan 40 mg capsulas duras<br>gastro-resistentes  | not available                   | 4143798                          | ARISTO PHARMA IBERIA, S.L.            | PT  |
| Omeprazol Rompharm 20 mg<br>capsule gastrozistente   | not available                   | 9294/2016/01                     | S.C. ROMPHARM COMPANY<br>S.R.L.       | RO  |
| Omeprazol AL T 40                                    | not available                   | 50281.00.00                      | ALIUD PHARMA GMBH                     | DE  |
| Losec 10 mg Kapseln                                  | NL/H/2081/001                   | 1-20934                          | ASTRAZENECA OSTERREICH<br>GMBH        | AT  |
| Losec 10 mg gyomornedv-<br>ellenálló kemény kapszula | NL/H/2081/001                   | OGYI-T-5114/02                   | ASTRAZENECA KFT.                      | HU  |
| Losec 10 mg gyomornedv-<br>ellenálló kemény kapszula | NL/H/2081/001                   | OGYI-T-5114/03                   | ASTRAZENECA KFT.                      | HU  |
| MOPRAL 10 mg, gélule gastro-<br>résistante           | NL/H/2081/001                   | NL 19623                         | ASTRAZENECA S.A.S.                    | FR  |
| Losec 20 mg Kapseln                                  | NL/H/2081/002                   | 1-19207                          | ASTRAZENECA OSTERREICH<br>GMBH        | AT  |
| MOPRAL 20 mg, gélule gastro-<br>résistante           | NL/H/2081/002                   | NL 14652                         | ASTRAZENECA S.A.S.                    | FR  |
| Losec 40 mg, maagsapresistente<br>capsules, hard     | NL/H/2081/003                   | RVG 14905                        | ASTRAZENECA BV                        | NL  |

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| Losec Injectie 4 mg/ml, poeder<br>en oplosmiddel voor oplossing<br>voor injectie | NL/H/2081/004                   | RVG 12439                        | ASTRAZENECA BV                            | NL  |
| Antra 10 mg capsule rigide<br>gastroresistenti                                   | NL/H/2081/001                   | 28245138                         | ASTRAZENECA S.P.A.                        | IT  |
| Losec 10 mg, maagsapresistente<br>capsules, hard                                 | NL/H/2081/001                   | RVG 16745                        | ASTRAZENECA BV                            | NL  |
| Antra 10 mg capsule rigide<br>gastroresistenti                                   | NL/H/2081/001                   | 28245114                         | ASTRAZENECA S.P.A.                        | IT  |
| Losec 20 mg gyomornedv-<br>ellenálló kemény kapszula                             | NL/H/2081/002                   | OGYI-T-5114/04                   | ASTRAZENECA KFT.                          | HU  |
| Antra 10 mg capsule rigide<br>gastroresistenti                                   | NL/H/2081/001                   | 28245126                         | ASTRAZENECA S.P.A.                        | IT  |
| Losec 20 mg cápsulas   | NL/H/2081/002                   | 8686915                          | ASTRAZENECA PRODUTOS<br>FARMACEUTICOS LDA | PT  |
| Losec 10 mg hard capsules  | NL/H/2081/001                   | PL 17901/0132                    | ASTRAZENECA UK LIMITED                    | UK  |
| Losec 20 mg cápsulas   | NL/H/2081/002                   | 8686907                          | ASTRAZENECA PRODUTOS<br>FARMACEUTICOS LDA | PT  |
| Losec 20 mg gyomornedv-<br>ellenálló kemény kapszula                             | NL/H/2081/002                   | OGYI-T-5114/05                   | ASTRAZENECA KFT.                          | HU  |
| Losec, kapsułki dojelitowe,<br>twarde, 20 mg                                     | NL/H/2081/002                   | R/1937                           | ASTRAZENECA AB                            | PL  |
| Losec 20 mg gyomornedv-<br>ellenálló kemény kapszula                             | NL/H/2081/002                   | OGYI-T-5114/06                   | ASTRAZENECA KFT.                          | HU  |
| Antra 20 mg capsule rigide<br>gastroresistenti                                   | NL/H/2081/002                   | 028245090                        | ASTRAZENECA S.P.A.                        | IT  |
| Losec 20 mg hard capsules  | NL/H/2081/002                   | PL 17901/0133                    | ASTRAZENECA UK LIMITED                    | UK  |
| Losec 20 mg cápsulas duras<br>gastroresistentes                                  | NL/H/2081/002                   | 58.377                           | ASTRAZENECA<br>FARMACÉUTICA SPAIN, S.A.   | ES  |

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| Losec 20 mg, maagsapresistente capsules, hard                       | NL/H/2081/002                   | RVG 12438                        | ASTRAZENECA BV                         | NL  |
| Losec 20 mg cápsulas  | NL/H/2081/002                   | 8686923                          | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA | PT  |
| Losec 20 mg cápsulas  | NL/H/2081/002                   | 8686931                          | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA | PT  |
| Losec 40 mg pulver till infusionsvätska, lösning                    | NL/H/2081/005                   | 11188                            | ASTRAZENECA AB                         | SE  |
| Antra 40 mg capsule rigide gastroresistenti                         | NL/H/2081/003                   | 02845037                         | ASTRAZENECA S.P.A.                     | IT  |
| Losec 40 mg hard capsules   | NL/H/2081/003                   | PL 17901/0134                    | ASTRAZENECA UK LIMITED                 | UK  |
| Losec 40 mg pulver och vätska till injektionsvätska, lösning        | NL/H/2081/004                   | 10724                            | ASTRAZENECA AB                         | SE  |
| Losec Infuus 40 mg, poeder voor oplossing voor intraveneuze infusie | NL/H/2081/005                   | RVG 14439                        | ASTRAZENECA BV                         | NL  |
| Losec-Mups 10 mg, comprimés gastro-résistants                       | NL/H/2081/006                   | BE206945                         | ASTRAZENECA S.A. / N.V.                | BE  |
| Losec-Mups 10 mg, maagsapresistente tabletten                       | NL/H/2081/006                   | BE206945                         | ASTRAZENECA S.A. / N.V.                | BE  |
| Losec Mups 10 mg γαστροανθεκτικά δισκία                             | NL/H/2081/006                   | 18063                            | ASTRAZENECA AB                         | CY  |
| Losec-Mups 10 mg, comprimés gastro-résistants                       | NL/H/2081/006                   | BE415335                         | ASTRAZENECA S.A. / N.V.                | BE  |
| LOSEC, ENTEROTABLETTER 10 MG  | NL/H/2081/006                   | 18755                            | ASTRAZENECA A/S                        | DK  |
| Antra MUPS® 10 mg magensaftresistente Tabletten                     | NL/H/2081/006                   | 40292.02.00                      | ASTRAZENECA GMBH                       | DE  |

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|--|---|--|---|---|
| Losec-Mups 10 mg,<br>maagsapresistente tabletten       | NL/H/2081/006                           | BE415335                                 | ASTRAZENECA S.A. / N.V.                       | BE  |
| Losec MUPS 10 mg gastro-<br>resistant tablets          | NL/H/2081/006                           | 046/00301                                | ASTRAZENECA UK LIMITED                        | MT  |
| Losec® MUPS® 10 mg<br>enterotabletti                   | NL/H/2081/006                           | 12832                                    | ASTRAZENECA OY                                | FI  |
| Losec MUPS 10mg gastro-<br>resistant tablets           | NL/H/2081/006                           | PA 970/44/6                              | ASTRAZENECA UK LIMITED                        | IE  |
| Losec-Mups 10 mg, 10 mg<br>comprimés gastro-résistants | NL/H/2081/006                           | 2006028429                               | ASTRAZENECA S.A. / N.V.                       | LU  |
| Losec-Mups 20 mg, 20 mg<br>comprimés gastro-résistants | NL/H/2081/008                           | BE415344                                 | ASTRAZENECA S.A. / N.V.                       | BE  |
| Losec MUPS 10 mg,<br>maagsapresistente tabletten       | NL/H/2081/006                           | RVG 21683                                | ASTRAZENECA BV                                | NL  |
| Losec-Mups 20 mg, 20 mg<br>comprimés gastro-résistants | NL/H/2081/008                           | BE206954                                 | ASTRAZENECA S.A. / N.V.                       | BE  |
| Losec MUPS 20 mg gastro-<br>resistant tablets          | NL/H/2081/008                           | 046/00302                                | ASTRAZENECA UK LIMITED                        | MT  |
| Losec MUPS 20 mg,<br>maagsapresistente tabletten       | NL/H/2081/008                           | RVG 21684                                | ASTRAZENECA BV                                | NL  |
| Losec 10 mg enterotabletter                            | NL/H/2081/006                           | 13670                                    | ASTRAZENECA AB                                | SE  |
| Losec® MUPS® 40 mg<br>enterotabletti                   | NL/H/2081/010                           | 12834                                    | ASTRAZENECA OY                                | FI  |
| Losec MUPS 10 mg gastro-<br>resistant tablets          | NL/H/2081/006                           | PL 17901/0137                            | ASTRAZENECA UK LIMITED                        | UK  |
| Losec MUPS 20 mg gastro-<br>resistant tablets          | NL/H/2081/008                           | PL 17901/0138                            | ASTRAZENECA UK LIMITED                        | UK  |
| Losec-Mups 20 mg,<br>maagsapresistente tabletten       | NL/H/2081/008                           | BE415344                                 | ASTRAZENECA S.A. / N.V.                       | BE  |

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| Losec Mups 20 mg<br>γαστροανθεκτικά δισκία             | NL/H/2081/008                   | 18064                            | ASTRAZENECA AB                        | CY  |
| Losec-Mups 40 mg, comprimés<br>gastro-résistants       | NL/H/2081/010                   | BE415353                         | ASTRAZENECA S.A. / N.V.               | BE  |
| Losec MUPS 40 mg gastro-<br>resistant tablets          | NL/H/2081/010                   | PL 17901/0139                    | ASTRAZENECA UK LIMITED                | UK  |
| Losec-Mups 40 mg,<br>maagsapresistente tabletten       | NL/H/2081/010                   | BE415353                         | ASTRAZENECA S.A. / N.V.               | BE  |
| Losec MUPS 40 mg gastro-<br>resistant tablets          | NL/H/2081/010                   | PA 970/44/8                      | ASTRAZENECA UK LIMITED                | IE  |
| Losec 40 mg enterotabletter                            | NL/H/2081/010                   | 13672                            | ASTRAZENECA AB                        | SE  |
| Losec-Mups 40 mg, 40 mg<br>comprimés gastro-résistants | NL/H/2081/010                   | 2006028431                       | ASTRAZENECA S.A. / N.V.               | LU  |
| Losec  | NL/H/2081/008                   | 18756                            | ASTRAZENECA A/S                       | DK  |
| Losec-Mups 20 mg, 20 mg<br>comprimés gastro-résistants | NL/H/2081/008                   | 2006028430                       | ASTRAZENECA S.A. / N.V.               | LU  |
| Losec-Mups 20 mg,<br>maagsapresistente tabletten       | NL/H/2081/008                   | BE206954                         | ASTRAZENECA S.A. / N.V.               | BE  |
| Losec 20 mg enterotabletter                            | NL/H/2081/008                   | 13671                            | ASTRAZENECA AB                        | SE  |
| Antra MUPS® 20 mg<br>magensaftresistente Tabletten     | NL/H/2081/008                   | 39993.00.00                      | ASTRAZENECA GMBH                      | DE  |
| Losec MUPS 20 mg gastro-<br>resistant tablets          | NL/H/2081/008                   | PA 970/44/7                      | ASTRAZENECA UK LIMITED                | IE  |
| Losec-Mups 40 mg,<br>maagsapresistente tabletten       | NL/H/2081/010                   | BE206963                         | ASTRAZENECA S.A. / N.V.               | BE  |
| Losec® MUPS® 20 mg<br>enterotabletti                   | NL/H/2081/008                   | 12833                            | ASTRAZENECA OY                        | FI  |
| Losec-Mups 40 mg, comprimés<br>gastro-résistants       | NL/H/2081/010                   | BE206963                         | ASTRAZENECA S.A. / N.V.               | BE  |

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| Losec MUPS enterotablet 10 mg                            | NL/H/2081/006                   | 97-452                           | ASTRAZENECA AS                        | NO  |
| Losec MUPS enterotablet 20 mg                            | NL/H/2081/008                   | 97-453                           | ASTRAZENECA AS                        | NO  |
| Losec 10 mg magasýrupolnar töflur                        | NL/H/2081/006                   | 970401 (IS)                      | ASTRAZENECA A/S                       | IS  |
| Losec 20 mg magasýrupolnar töflur                        | NL/H/2081/008                   | 970402 (IS)                      | ASTRAZENECA A/S                       | IS  |
| Losec 10 mg capsule rigide gastroresistenti              | IT/H/0254/001                   | 026804082                        | ASTRAZENECA AB                        | IT  |
| Losec 10 mg capsule rigide gastroresistenti              | IT/H/0254/001                   | 026804094                        | ASTRAZENECA AB                        | IT  |
| Losec 10 mg capsule rigide gastroresistenti              | IT/H/0254/001                   | 026804118                        | ASTRAZENECA AB                        | IT  |
| Losec 20 mg capsule rigide gastroresistenti              | IT/H/0254/002                   | 026804106                        | ASTRAZENECA AB                        | IT  |
| Losec 40 mg capsule rigide gastroresistenti              | IT/H/0254/003                   | 026804056                        | ASTRAZENECA AB                        | IT  |
| DOLINTOL 40 mg Cápsulas duras gastrorresistentes         | not available                   | 68.132                           | ABABOR PHARMACEUTICALS, S.L.          | ES  |
| Omeprazol ABDrug 40 mg cápsulas duras gastrorresistentes | NL/H/2940/003                   | 79487                            | MABO-FARMA, S.A.                      | ES  |
| Antra® Magensaftresistente Tablette mit 20 mg Omeprazol  | not available                   | 40292.00.00                      | BAYER VITAL GMBH                      | DE  |
| MOPRALPRO 20 mg, comprimé gastro-résistant               | not available                   | 34009 375 328 9 1                | BAYER HEALTHCARE                      | FR  |
| MOPRALPRO 20 mg, comprimé gastro-résistant               | not available                   | 34009 375 324 3 3                | BAYER HEALTHCARE                      | FR  |



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| MOPRALPRO 20 mg, comprimé<br>gastro-résistant               | not available                   | 34009 375 326 6 2                | BAYER HEALTHCARE                      | FR  |
| Losec 20 mg -enterotabletti                                 | not available                   | 27596                            | BAYER OY                              | FI  |
| Antra® 20 mg -<br>magensaftresistente Tabletten             | not available                   | 1-29470                          | BAYER AUSTRIA GMBH                    | AT  |
| Losecosan 20 mg,<br>maagsapresistente tablet                | not available                   | RVG 25213                        | BAYER BV                              | NL  |
| Antra® Magensaftresistente<br>Tablette mit 20 mg Omeprazol  | not available                   | 39994.00.00                      | BAYER VITAL GMBH                      | DE  |
| MOPRALPRO 20 mg, comprimé<br>gastro-résistant               | not available                   | 34009 375 327 2 3                | BAYER HEALTHCARE                      | FR  |
| Losecosan 10 mg,<br>maagsapresistente tablet                | not available                   | RVG 25212                        | BAYER BV                              | NL  |
| Omeprazol Teva 40 mg<br>magensaftresistente Hartkapseln     | UK/H/4493/003                   | BE427935                         | TEVA PHARMA BELGIUM<br>N.V./S.A       | BE  |
| Omeprazol Teva 40 mg<br>maagsapresistente capsules,<br>hard | UK/H/4493/003                   | BE427944                         | TEVA PHARMA BELGIUM<br>N.V./S.A       | BE  |
| Omeprazol Teva 40 mg<br>magensaftresistente Hartkapseln     | UK/H/4493/003                   | BE427944                         | TEVA PHARMA BELGIUM<br>N.V./S.A       | BE  |
| Omeprazol Teva 40 mg<br>maagsapresistente capsules,<br>hard | UK/H/4493/003                   | BE427935                         | TEVA PHARMA BELGIUM<br>N.V./S.A       | BE  |
| Omeprazol Teva 40 mg gélules<br>gastro-résistantes          | UK/H/4493/003                   | BE427935                         | TEVA PHARMA BELGIUM<br>N.V./S.A       | BE  |
| Omeprazol Teva 40 mg gélules<br>gastro-résistantes          | UK/H/4493/003                   | BE427944                         | TEVA PHARMA BELGIUM<br>N.V./S.A       | BE  |

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| Omeprazol-Teva 40 mg<br>gyomornedv-ellenálló kemény<br>kapszula | UK/H/4493/003                   | OGYI-T-22326/03                  | TEVA GYÓGYSZERGYÁR ZRT                | HU  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti        | NL/H/0974/001                   | 038025476                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti        | NL/H/0974/001                   | 038025490                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti        | NL/H/0974/001                   | 038025514                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti        | NL/H/0974/001                   | 038025538                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti        | NL/H/0974/001                   | 038025540                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti        | NL/H/0974/002                   | 038025553                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti        | NL/H/0974/002                   | 038025488                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti        | NL/H/0974/002                   | 038025565                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti        | NL/H/0974/002                   | 038025526                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti        | NL/H/0974/002                   | 038025502                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti        | NL/H/0974/002                   | 038025401                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti        | NL/H/0974/001                   | 038025122                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti        | NL/H/0974/001                   | 038025033                        | TEVA ITALIA S.R.L.                    | IT  |

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| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                           | 038025363                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025072                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025021                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                           | 038025336                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025197                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                           | 038025247                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                           | 038025324                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                           | 038025300                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025134                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                           | 038025250                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                           | 038025399                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                           | 038025312                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025096                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025173                                | TEVA ITALIA S.R.L.                            | IT  |

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| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025045                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025159                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025108                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025161                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025060                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025110                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                           | 038025375                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                           | 038025413                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025058                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025223                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                           | 038025286                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025146                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                           | 038025464                                | TEVA ITALIA S.R.L.                            | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                           | 038025211                                | TEVA ITALIA S.R.L.                            | IT  |

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| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                   | 038025185                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                   | 038025351                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                   | 038025387                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                   | 038025019                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                   | 038025262                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                   | 038025449                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                   | 038025209                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                   | 038025425                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                   | 038025235                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                   | 038025298                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 10 mg capsule<br>rigide gastroresistenti | NL/H/0974/001                   | 038025084                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazol Teva 10 mg<br>enterokapslar, hårda             | NL/H/0974/003                   | 24807                            | TEVA SWEDEN AB                        | SE  |
| Omeprazol Teva 20 mg<br>enterokapslar, hårda             | NL/H/0974/002                   | 24806                            | TEVA SWEDEN AB                        | SE  |
| Omeprazol Teva 10 mg<br>enterokapslar, hårda             | NL/H/0974/001                   | 24805                            | TEVA SWEDEN AB                        | SE  |

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| Ulzol 10 mg trde<br>gastrorezistentne kapsule            | NL/H/0974/001                   | H/10/01175/001                   | TEVA PHARMA B.V.                      | SI  |
| Ulzol 20 mg trde<br>gastrorezistentne kapsule            | NL/H/0974/001                   | H/10/01175/031                   | TEVA PHARMA B.V.                      | SI  |
| Ulzol 20 mg trde<br>gastrorezistentne kapsule            | NL/H/0974/002                   | H/10/01175/030                   | TEVA PHARMA B.V.                      | SI  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                   | 038025274                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                   | 038025348                        | TEVA ITALIA S.R.L.                    | IT  |
| Omeprazolo Teva 20 mg capsule<br>rigide gastroresistenti | NL/H/0974/002                   | 038025452                        | TEVA ITALIA S.R.L.                    | IT  |
| Ulzol 40 mg trde<br>gastrorezistentne kapsule            | NL/H/0974/003                   | H/10/01175/059                   | TEVA PHARMA B.V.                      | SI  |
| Omeprazol AL T 20  | DE/H/0320/001                   | 50197.00.00                      | ALIUD PHARMA GMBH                     | DE  |
| Omeprazol G.L. 40 mg-Kapseln                             | not available                   | 1-27667                          | G.L. PHARMA GMBH                      | AT  |
| Losec 40mg gastro-resistant<br>capsule, hard             | NL/H/2081/003                   | 5563/29-1-2013                   | ASTRAZENECA S.A                       | GR  |
| LOSECâ MUPSâ   | NL/H/2081/010                   | 5567/29-1-2013                   | ASTRAZENECA S.A                       | GR  |
| Losec Mups 20 mg<br>γαστροανθεκτικά δισκία               | NL/H/2081/008                   | 5566/29-1-2013                   | ASTRAZENECA S.A                       | GR  |
| LOSECâ MUPSâ   | NL/H/2081/006                   | 5565/29-1-2013                   | ASTRAZENECA S.A                       | GR  |
| Losec 20mg gastro-resistant<br>capsule, hard             | NL/H/2081/002                   | 5561/29.01.2013                  | ASTRAZENECA S.A                       | GR  |
| Losec 10mg gastro-resistant<br>capsule, hard             | NL/H/2081/001                   | 5564/29.01.2013                  | ASTRAZENECA S.A                       | GR  |
| Mezzopram 20 mg Dispersible<br>Gastro-resistant Tablets  | NL/H/1651/002                   | PL 04416/1078                    | SANDOZ LTD                            | UK  |

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| Mezzopram 10 mg Dispersible<br>Gastro-resistant Tablets          | NL/H/1651/001                   | PL 04416/1077                    | SANDOZ LTD                            | UK  |
| Mezzopram 40 mg Dispersible<br>Gastro-resistant Tablets          | NL/H/1651/003                   | PL 04416/1079                    | SANDOZ LTD                            | UK  |
| OMEPRAZOL TERAPIA 20 mg<br>capsule gastrorezistente              | not available                   | 86/2007/01                       | TERAPIA S.A.                          | RO  |
| Omeprazol Almus 40 mg cápsulas<br>duras gastrorresistentes       | NL/H/1806/001                   | 72679                            | ALMUS FARMACEUTICA S.A                | ES  |
| Ulceral 20 mg cápsulas duras<br>gastrorresistentes               | not available                   | 60.023                           | TEDEC-MEIJ FARMA, S.A.                | ES  |
| Ulceral 40 mg cápsulas duras<br>gastrorresistentes               | not available                   | 64.753                           | TEDEC-MEIJ FARMA, S.A.                | ES  |
| Omeprazol Apofri 20 mg<br>enterokapslar, hårda                   | not available                   | 43880                            | APOFRI AB                             | SE  |
| Omeprazol cinfa 40 mg cápsulas<br>duras gastrorresistentes       | NL/H/2939/003/DC                | 78.891                           | LABORATORIOS CINFA, S.A.              | ES  |
| Omeprazol CF 10 mg,<br>maagsapresistente capsules,<br>hard       | NL/H/1422/001                   | RVG 102162                       | CENTRAFARM B.V.                       | NL  |
| Omestad 10 mg enterokapseli,<br>kova                             | NL/H/1422/001                   | 25257                            | STADA ARZNEIMITTEL AG                 | FI  |
| Omeprazole EG 10 mg gélules<br>gastro-résistantes                | NL/H/1422/001                   | 2013110433                       | EUROGENERICS N.V./S.A.                | LU  |
| Омепразол СТАДА 10 mg<br>стомашно-устойчиви капсули,<br>твърди   | NL/H/1422/001                   | 20090433                         | STADA ARZNEIMITTEL AG                 | BG  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965101                        | EG S.P.A.                             | IT  |

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| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965063                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965214                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965190                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965099                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965048                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965253                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965036                        | EG S.P.A.                             | IT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes             | NL/H/1422/001                   | 5288105                          | CICLUM FARMA UNIPessoal<br>LDA.       | PT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965125                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965152                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965149                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965113                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965238                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965226                        | EG S.P.A.                             | IT  |



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| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes             | NL/H/1422/001                   | 5288121                          | CICLUM FARMA UNIPessoal<br>LDA.       | PT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965176                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965188                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965087                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965240                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965051                        | EG S.P.A.                             | IT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes             | NL/H/1422/001                   | 5288071                          | CICLUM FARMA UNIPessoal<br>LDA.       | PT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965024                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965075                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965137                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965164                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965012                        | EG S.P.A.                             | IT  |
| OMEPRAZOLO EUROGENERICI 10<br>mg capsule rigide gastroresistenti | NL/H/1422/001                   | 038965202                        | EG S.P.A.                             | IT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes             | NL/H/1422/001                   | NL/H/1422/001                    | CICLUM FARMA UNIPessoal<br>LDA.       | PT  |

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| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes | NL/H/1422/001                           | NL/H/1422/001                            | CICLUM FARMA UNIPessoal<br>LDA.               | PT  |

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| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes        | NL/H/1422/001                   | NL/H/1422/001                    | CICLUM FARMA UNIPessoal<br>LDA.       | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes        | NL/H/1422/001                   | NL/H/1422/001                    | CICLUM FARMA UNIPessoal<br>LDA.       | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes        | NL/H/1422/001                   | NL/H/1422/001                    | CICLUM FARMA UNIPessoal<br>LDA.       | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes        | NL/H/1422/001                   | NL/H/1422/001                    | CICLUM FARMA UNIPessoal<br>LDA.       | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes        | NL/H/1422/001                   | NL/H/1422/001                    | CICLUM FARMA UNIPessoal<br>LDA.       | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes        | NL/H/1422/001                   | 5288113                          | CICLUM FARMA UNIPessoal<br>LDA.       | PT  |
| Omeprazol Tartet 10 mg Cápsulas<br>gastroresistentes        | NL/H/1422/001                   | 5288063                          | CICLUM FARMA UNIPessoal<br>LDA.       | PT  |
| PARIZAC 20 mg cápsulas duras<br>gastroresistentes           | not available                   | 58.466                           | LACER S.A.                            | ES  |
| PARIZAC 40 mg cápsulas duras<br>gastroresistentes           | not available                   | 67.222                           | LACER S.A.                            | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                   | 77389                            | ZENTIVA, K.S.                         | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                   | 77389                            | ZENTIVA, K.S.                         | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                   | 77389                            | ZENTIVA, K.S.                         | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                   | 77389                            | ZENTIVA, K.S.                         | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                   | 77389                            | ZENTIVA, K.S.                         | ES  |

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| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastroresistentes | UK/H/4423/003                           | 77389                                    | ZENTIVA, K.S.                                 | ES  |

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|--|---------------------------------|----------------------------------|--|---|
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastrorresistentes | UK/H/4423/003                   | 77389                            | ZENTIVA, K.S.  | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastrorresistentes | UK/H/4423/003                   | 77389                            | ZENTIVA, K.S.  | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastrorresistentes | UK/H/4423/003                   | 77389                            | ZENTIVA, K.S.  | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastrorresistentes | UK/H/4423/003                   | 77389                            | ZENTIVA, K.S.  | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastrorresistentes | UK/H/4423/003                   | 77389                            | ZENTIVA, K.S.  | ES  |
| Omeprazol Zentiva 40 mg<br>cápsulas duras gastrorresistentes | UK/H/4423/003                   | 77389                            | ZENTIVA, K.S.  | ES  |
| Reglacid® 10 mg comprimés<br>gastro-résistants               | not available                   | BE442897                         | LABORATOIRES SMB S.A.                                | BE  |
| Reglacid® 10 mg<br>maagsapresistente tabletten               | not available                   | BE442897                         | LABORATOIRES SMB S.A.                                | BE  |
| Reglacid® 10 mg<br>magensaftresistente Tabletten             | not available                   | BE442897                         | LABORATOIRES SMB S.A.                                | BE  |
| Reglacid® 20 mg comprimés<br>gastro-résistants               | not available                   | BE442906                         | LABORATOIRES SMB S.A.                                | BE  |
| Reglacid® 20 mg<br>maagsapresistente tabletten               | not available                   | BE442906                         | LABORATOIRES SMB S.A.                                | BE  |
| Reglacid® 20 mg<br>magensaftresistente Tabletten             | not available                   | BE442906                         | LABORATOIRES SMB S.A.                                | BE  |
| Omeprazol Mabo 40 mg cápsulas<br>duras gastrorresistentes    | not available                   | 79.978                           | MABO-FARMA, S.A.                                     | ES  |
| Pepticum 40 mg cápsulas duras<br>gastrorresistentes          | not available                   | 64.881                           | LABORATORIOS<br>MEDICAMENTOS<br>INTERNACIONALES S.A. | ES  |

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|---|---------------------------------|----------------------------------|---------------------------------------|---|
| Omeprazol Mabo-Farma 40 mg<br>cápsulas duras gastrorresistentes | not available                   | 65.013                           | MABO-FARMA, S.A.                      | ES  |
| OMEPRAZOL CINFALAB 40 MG<br>CÁPSULAS DURAS<br>GASTRORESISTENTES | not available                   | 65570                            | LABORATORIOS CINFA, S.A.              | ES  |
| Omeprazol AL T 40   | not available                   | 50281.00.00                      | ALIUD PHARMA GMBH                     | DE  |
| Omeprazol "Aurobindo", hard<br>capsules 40 mg                   | MT/H/0120/003                   | 46496                            | AUROBINDO PHARMA<br>(MALTA) LIMITED   | DK  |
| Omeprazol "Aurobindo", hårde<br>enterokapsler 10 mg             | MT/H/0120/001                   | 46494                            | AUROBINDO PHARMA<br>(MALTA) LIMITED   | DK  |
| Omeprazol "Aurobindo", hårde<br>enterokapsler 20 mg             | MT/H/0120/002                   | 46495                            | AUROBINDO PHARMA<br>(MALTA) LIMITED   | DK  |
| Romep 10 mg gastro-resistant<br>capsules, hard                  | MT/H/0120/001                   | PA 1050/15/1                     | MILPHARM LIMITED                      | IE  |
| Romep 20 mg gastro-resistant<br>capsules, hard                  | MT/H/0120/002                   | PA 1050/15/2                     | MILPHARM LIMITED                      | IE  |
| Romep 40 mg gastro-resistant<br>capsules, hard                  | MT/H/0120/003                   | PA 1050/15/3                     | MILPHARM LIMITED                      | IE  |
| Omeprazole Aurobindo 10 mg<br>gastro-resistant capsules, hard   | MT/H/0120/001                   | MA807/01701                      | AUROBINDO PHARMA<br>(MALTA) LIMITED   | MT  |
| Omeprazole Aurobindo 20 mg<br>gastro-resistant capsules, hard   | MT/H/0120/002                   | MA807/01702                      | AUROBINDO PHARMA<br>(MALTA) LIMITED   | MT  |
| Omeprazole Aurobindo 40 mg<br>gastro-resistant capsules, hard   | MT/H/0120/003                   | MA807/01703                      | AUROBINDO PHARMA<br>(MALTA) LIMITED   | MT  |
| Omeprazol Aurobindo 40 mg<br>kapsulki dojelitowe, twarde        | MT/H/0120/003                   | 18898                            | AUROBINDO PHARMA<br>(MALTA) LIMITED   | PL  |
| Omeprazol Aurobindo 10 mg<br>enterokapslar, hårda               | MT/H/0120/001                   | 43843                            | AUROBINDO PHARMA<br>(MALTA) LIMITED   | SE  |

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|---|---------------------------------|----------------------------------|---------------------------------------|---|
| Omeprazol Aurobindo 20 mg<br>enterokapslar, hårda     | MT/H/0120/002                   | 43844                            | AUROBINDO PHARMA<br>(MALTA) LIMITED   | SE  |
| Omeprazol Aurobindo 40 mg<br>enterokapslar, hårda     | MT/H/0120/003                   | 43845                            | AUROBINDO PHARMA<br>(MALTA) LIMITED   | SE  |
| Omeprazol "Aurobindo", hårde<br>enterokapsler 10 mg   | MT/H/0120/001                   | 46494                            | AUROBINDO PHARMA<br>(MALTA) LIMITED   | DK  |
| Omeprazol "Aurobindo", hårde<br>enterokapsler 20 mg   | MT/H/0120/002                   | 46495                            | AUROBINDO PHARMA<br>(MALTA) LIMITED   | DK  |
| Omeprazol Aurobindo 20 mg<br>capsule gastrorezistente | MT/H/0120/002                   | 8869/2016/01                     | AUROBINDO PHARMA<br>(MALTA) LIMITED   | RO  |
| Omeprazol Aurobindo 20 mg<br>capsule gastrorezistente | MT/H/0120/002                   | 8869/2016/02                     | AUROBINDO PHARMA<br>(MALTA) LIMITED   | RO  |
| Omeprazol Aurobindo 20 mg<br>capsule gastrorezistente | MT/H/0120/002                   | 8869/2016/03                     | AUROBINDO PHARMA<br>(MALTA) LIMITED   | RO  |
| Omeprazol Aurobindo 20 mg<br>capsule gastrorezistente | MT/H/0120/002                   | 8869/2016/04                     | AUROBINDO PHARMA<br>(MALTA) LIMITED   | RO  |
| Omeprazol Aurobindo 20 mg<br>capsule gastrorezistente | MT/H/0120/002                   | 8869/2016/05                     | AUROBINDO PHARMA<br>(MALTA) LIMITED   | RO  |
| Omeprazol Aurobindo 20 mg<br>capsule gastrorezistente | MT/H/0120/002                   | 8869/2016/06                     | AUROBINDO PHARMA<br>(MALTA) LIMITED   | RO  |
| Omeprazol Aurobindo 20 mg<br>capsule gastrorezistente | MT/H/0120/002                   | 8869/2016/07                     | AUROBINDO PHARMA<br>(MALTA) LIMITED   | RO  |
| Omeprazol Aurobindo 20 mg<br>capsule gastrorezistente | MT/H/0120/002                   | 8869/2016/08                     | AUROBINDO PHARMA<br>(MALTA) LIMITED   | RO  |
| Omeprazol Aurobindo 20 mg<br>capsule gastrorezistente | MT/H/0120/002                   | 8869/2016/09                     | AUROBINDO PHARMA<br>(MALTA) LIMITED   | RO  |
| Omeprazol Aurobindo 20 mg<br>capsule gastrorezistente | MT/H/0120/002                   | 8869/2016/10                     | AUROBINDO PHARMA<br>(MALTA) LIMITED   | RO  |

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|--|---|--|---|---|
| Omeprazol Aurobindo 20 mg capsule gastroresistente | MT/H/0120/002                           | 8869/2016/11                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 20 mg capsule gastroresistente | MT/H/0120/002                           | 8869/2016/12                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 20 mg capsule gastroresistente | MT/H/0120/002                           | 8869/2016/13                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 20 mg capsule gastroresistente | MT/H/0120/002                           | 8869/2016/14                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 20 mg capsule gastroresistente | MT/H/0120/002                           | 8869/2016/15                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 20 mg capsule gastroresistente | MT/H/0120/002                           | 8869/2016/16                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 20 mg capsule gastroresistente | MT/H/0120/002                           | 8869/2016/17                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 20 mg capsule gastroresistente | MT/H/0120/002                           | 8869/2016/18                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 20 mg capsule gastroresistente | MT/H/0120/002                           | 8869/2016/19                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/01                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/02                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/03                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/04                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/05                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |



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|--|---|--|---|---|
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/06                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/07                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/08                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/09                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/10                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/11                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/12                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/13                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/14                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 40 mg capsule gastroresistente | MT/H/0120/003                           | 8870/2016/15                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente | MT/H/0120/001                           | 8868/2016/01                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente | MT/H/0120/001                           | 8868/2016/02                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente | MT/H/0120/001                           | 8868/2016/03                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente | MT/H/0120/001                           | 8868/2016/04                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |

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|--|---|--|---|---|
| Omeprazol Aurobindo 10 mg capsule gastroresistente         | MT/H/0120/001                           | 8868/2016/05                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente         | MT/H/0120/001                           | 8868/2016/06                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente         | MT/H/0120/001                           | 8868/2016/07                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente         | MT/H/0120/001                           | 8868/2016/08                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente         | MT/H/0120/001                           | 8868/2016/09                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente         | MT/H/0120/001                           | 8868/2016/10                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente         | MT/H/0120/001                           | 8868/2016/11                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente         | MT/H/0120/001                           | 8868/2016/12                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente         | MT/H/0120/001                           | 8868/2016/13                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente         | MT/H/0120/001                           | 8868/2016/14                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol Aurobindo 10 mg capsule gastroresistente         | MT/H/0120/001                           | 8868/2016/15                             | AUROBINDO PHARMA (MALTA) LIMITED              | RO  |
| Omeprazol ratiopharm 10 mg magensaftresistente Hartkapseln | AT/H/0273/001                           | 1-25634                                  | RATIOPHARM ARZNEIMITTEL VERTRIEBS-GMBH        | AT  |
| Omeprazol ratiopharm 40 mg magensaftresistente Hartkapseln | AT/H/0274/003                           | 1-25635                                  | RATIOPHARM ARZNEIMITTEL VERTRIEBS-GMBH        | AT  |
| Omeprazol ratiopharm 10 mg enterokapsel, hård              | FI/H/0176/001                           | 17463                                    | RATIOPHARM GMBH                               | FI  |

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|---|---|--|---|---|
| Omeprazol ratiopharm 40 mg enterokapsel, hård                 | FI/H/0176/003                           | 17464                                    | RATIOPHARM GMBH                               | FI  |
| Omeprazol Aristo 40 mg cápsulas duras gastrorresistentes      | not available                           | 67.273                                   | ARISTO PHARMA IBERIA, S.L.                    | ES  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082018                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082020                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082032                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082044                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082057                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082069                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082071                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082083                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082095                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082107                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082119                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082121                                | DOC GENERICI S.R.L.                           | IT  |

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|---|---|--|---|---|
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082133                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082145                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082158                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082160                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082172                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082184                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082196                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082208                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082210                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082222                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082234                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082246                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082259                                | DOC GENERICI S.R.L.                           | IT  |
| OMEPRAZOLO DOC Generici 10 mg capsule rigide gastroresistenti | NL/H/0973/001                           | 038082261                                | DOC GENERICI S.R.L.                           | IT  |
| Arapride 10 mg capsulas duras                                 | not available                           | 65.687                                   | ARAFARMA GROUP, S.A                           | ES  |

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|---|---------------------------------|----------------------------------|---------------------------------------|---|
| Arapride 40 mg capsulas duras<br>gastrorresistentes                         | not available                   | 65.688                           | ARAFARMA GROUP, S.A                   | ES  |
| Omeprazole 20mg Capsules  | UK/H/0799/002                   | PL 04416/0652                    | SANDOZ LTD                            | UK  |
| Omeprazol 1A Pharma 10 mg -<br>Kapseln                                      | not available                   | 1-24871                          | 1A PHARMA GMBH                        | AT  |
| Omeprazol 1A Pharma 20 mg -<br>Kapseln                                      | not available                   | 1-24869                          | 1A PHARMA GMBH                        | AT  |
| Omeprazol 1A Pharma 40 mg -<br>Kapseln                                      | not available                   | 1-24870                          | 1A PHARMA GMBH                        | AT  |
| Omepr Uno   | UK/H/4500/002                   | 779812                           | SANDOZ PHARMACEUTICALS<br>D.D.        | EE  |
| Omeprazole Sandoz 20 mg zarnās<br>šķīstošās cietās kapsulas                 | UK/H/4500/002                   | 12-0127                          | SANDOZ PHARMACEUTICALS<br>D.D.        | LV  |
| OMEPRAZOL SANDOZ  | UK/H/0799/003                   | 5930987                          | SANDOZ FARMACÊUTICA LDA.              | PT  |
| OMEPRAZOL SANDOZ  | UK/H/0799/003                   | 5931084                          | SANDOZ FARMACÊUTICA LDA.              | PT  |
| Omeprazol Sandoz 40 mg<br>cápsulas duras gastrorresistentes                 | UK/H/1024/003                   | 70288                            | SANDOZ FARMACÉUTICA, S.A.             | ES  |
| Omeprazol Sandoz Farmacéutica<br>40 mg cápsulas duras<br>gastrorresistentes | not available                   | 65.569                           | BEXAL FARMACÉUTICA S.A.               | ES  |
| Omeprazol Sandoz Farmacéutica<br>10 mg cápsulas duras<br>gastrorresistentes | not available                   | 65.517                           | SANDOZ FARMACÉUTICA, S.A.             | ES  |
| Omeprazol Liconsa 20 mg<br>capsulas duras gastrorresistentes                | not available                   | 58383                            | LABORATORIOS LICONSA, S.A.            | ES  |
| Ludea 10 mg gyomornedv-<br>ellenálló kemény kapszula                        | NL/H/0972/001                   | OGYI-T-20638/01                  | GEDEON RICHTER PLC.                   | HU  |
| Ludea 40 mg gyomornedv-<br>ellenálló kemény kapszula                        | NL/H/0972/003                   | OGYI-T-20638/03                  | GEDEON RICHTER PLC.                   | HU  |

| <b>Product Name<br/>(in authorisation country)</b> | <b>MRP/DCP Authorisation<br/>Number</b> | <b>National Authorisation<br/>Number</b> | <b>MAH of product in the<br/>Member State</b> | <b>Member State where<br/>product is authorised</b> |
|--|---|--|---|---|
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003012                                | S.F. GROUP SRL                                | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003024                                | S.F. GROUP SRL                                | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003036                                | S.F. GROUP SRL                                | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003048                                | S.F. GROUP SRL                                | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003051                                | S.F. GROUP SRL                                | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003063                                | S.F. GROUP SRL                                | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003075                                | S.F. GROUP SRL                                | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003087                                | S.F. GROUP SRL                                | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003099                                | S.F. GROUP SRL                                | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003101                                | S.F. GROUP SRL                                | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003113                                | S.F. GROUP SRL                                | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003125                                | S.F. GROUP SRL                                | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003137                                | S.F. GROUP SRL                                | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti       | NL/H/0972/001                           | 038003149                                | S.F. GROUP SRL                                | IT  |

| Product Name<br>(in authorisation country)                        | MRP/DCP Authorisation<br>Number | National Authorisation<br>Number | MAH of product in the<br>Member State  | Member State where<br>product is authorised |
|---|---------------------------------|----------------------------------|--|---|
| OMOLIN 10 mg capsule rigide gastroresistenti                      | NL/H/0972/001                   | 038003152                        | S.F. GROUP SRL                         | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti                      | NL/H/0972/001                   | 038003164                        | S.F. GROUP SRL                         | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti                      | NL/H/0972/001                   | 038003176                        | S.F. GROUP SRL                         | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti                      | NL/H/0972/001                   | 038003188                        | S.F. GROUP SRL                         | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti                      | NL/H/0972/001                   | 038003190                        | S.F. GROUP SRL                         | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti                      | NL/H/0972/001                   | 038003202                        | S.F. GROUP SRL                         | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti                      | NL/H/0972/001                   | 038003214                        | S.F. GROUP SRL                         | IT  |
| OMOLIN 10 mg capsule rigide gastroresistenti                      | NL/H/0972/001                   | 038003226                        | S.F. GROUP SRL                         | IT  |
| Omeprazol Aurovitas Spain 40 mg cápsulas duras gastrorresistentes | SE/H/0754/003                   | 72.146                           | AUROVITAS SPAIN,S.A.U.                 | ES  |
| Omeprazol ratiopharm 10 mg magensaftresistente Hartkapseln        | AT/H/0273/001                   | 1-25634                          | RATIOPHARM ARZNEIMITTEL VERTRIEBS-GMBH | AT  |
| Omeprazol STADA® 40 mg magensaftresistente Tabletten              | not available                   | 50280.00.00                      | STADAPHARM GMBH                        | DE  |
| Omeprazol "Medical Valley" enterokapsler, hårde, 10 mg            | NL/H/0973/001                   | 40443                            | MEDICAL VALLEY INVEST AB               | DK  |
| Omeprazol "Medical Valley" enterokapsler, hårde, 40 mg            | NL/H/0973/003                   | 40445                            | MEDICAL VALLEY INVEST AB               | DK  |