



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

15 October 2020  
EMA/686825/2020  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: mesalazine

Procedure no.: PSUSA - 00001990-202002

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| Product Name (in authorisation country)       | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|------------------------------|-------------------------------|------------------------------------|--|
| Salofalk 4 g/60 mL enemas                     | not available                | 12246                         | DR FALK PHARMA GMBH                | CY                                       |
| PENTASA, 1 g suposiidid                       | not available                | 145396                        | FERRING GMBH                       | EE                                       |
| Collitofalk 500 mg zetpillen                  | not available                | BE156606                      | DR. FALK PHARMA BENELUX B.V.       | BE                                       |
| Collitofalk 500 mg suppositoires              | not available                | BE156606                      | DR. FALK PHARMA BENELUX B.V.       | BE                                       |
| ASACOL 400 mg Gastro-resistant Tablets        | not available                | 19504                         | TILLOTTS PHARMA GMBH               | CY                                       |
| Pentasa 1 g čepíci                            | not available                | HR-H-729224011                | FERRING GMBH                       | HR                                       |
| Pentasa 2 g κοκκία παρατεταμένης αποδέσμευσης | DK/H/0140/002                | 021943                        | FERRING HELLAS MEPE                | CY                                       |
| PENTASA Sachet 4g prolonged release granules  | DK/H/0140/003                | PL 03194/0117                 | FERRING PHARMACEUTICALS LTD.       | UK                                       |
| Pentasa Sachet 4 g depotgranulat              | DK/H/0140/003                | 50369                         | FERRING LÄKEMEDEL AB               | SE                                       |
| Quintasa Sachet, depotgranulat                | DK/H/0140/003                | 53238                         | FERRING LÆGEMIDLER A/S             | DK                                       |

|  |               |                  |                        |    |
|--|---------------|------------------|------------------------|----|
| PENTASA Sachet 4g prolonged release granules   | DK/H/0140/003 | PA 1009/006/008  | FERRING IRELAND LTD.   | IE |
| Pentasa 4 g κοκκία παρατεταμένης αποδέσμευσης  | DK/H/0140/003 | 16611/05.03.2015 | FERRING HELLAS MEPE    | GR |
| Pentasa 4 g zrnca s podaljšanim sproščanjem    | DK/H/0140/003 | H/12/01236/005   | FERRING GMBH           | SI |
| Pentasa 2 g zrnca s podaljšanim sproščanjem    | DK/H/0140/002 | H/12/01236/003   | FERRING GMBH           | SI |
| Pentasa 4 g zrnca s podaljšanim sproščanjem    | DK/H/0140/003 | H/12/01236/004   | FERRING GMBH           | SI |
| Pentasa 4 g zrnca s podaljšanim sproščanjem    | DK/H/0140/003 | H/12/01236/006   | FERRING GMBH           | SI |
| Pentasa 4 g zrnca s podaljšanim sproščanjem    | DK/H/0140/003 | H/12/01236/007   | FERRING GMBH           | SI |
| PENTASA Sachet 4 g Retardgranulat              | DK/H/0140/003 | 91296.00.00      | FERRING GMBH           | DE |
| Pentasa 4 g granulado de liberación prolongada | DK/H/0140/003 | 79555            | FERRING S.A.U.         | ES |
| Quintasa Sachet, depotgranulat                 | DK/H/0140/001 | 18936            | FERRING LÆGEMIDLER A/S | DK |
| Quintasa Sachet, depotgranulat                 | DK/H/0140/002 | 36657            | FERRING LÆGEMIDLER A/S | DK |

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|---|---------------|----------------|----------------------|----|
| PENTASA Sachet 1000 mg Retardgranulat         | DK/H/0140/001 | 44367.00.00    | FERRING GMBH         | DE |
| PENTASA Xtend 2 g Retardgranulat Mesalazin    | DK/H/0140/002 | 67611.00.00    | FERRING GMBH         | DE |
| Pentasa 4 g κοκκία παρατεταμένης αποδέσμευσης | DK/H/140/003  | 022373         | FERRING HELLAS MEPE  | CY |
| Pentasa Sachet 1g prolonged-release granules  | DK/H/0140/001 | PA 1009/6/1    | FERRING IRELAND LTD. | IE |
| Pentasa Sachet 2g prolonged-release granules  | DK/H/0140/002 | PA 1009/6/6    | FERRING IRELAND LTD. | IE |
| Pentasa 2 g zrnca s podaljšanim sproščanjem   | DK/H/0140/002 | H/12/01236/001 | FERRING GMBH         | SI |
| Pentasa 2 g zrnca s podaljšanim sproščanjem   | DK/H/0140/002 | H/12/01236/002 | FERRING GMBH         | SI |
| Pentasa 1g granulada de liberación prolongada | DK/H/0140/001 | 62.670         | FERRING S.A.U.       | ES |
| Pentasa Sachet 1 g depotgranulat              | DK/H/0140/001 | 14752          | FERRING LÄKEMEDEL AB | SE |
| Pentasa Sachet 2 g depotgranulat              | DK/H/0140/002 | 25569          | FERRING LÄKEMEDEL AB | SE |

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|--|---------------|------------------|------------------------------|----|
| PENTASA Sachet 1g prolonged release granules       | DK/H/0140/001 | PL 03194/0075    | FERRING PHARMACEUTICALS LTD. | UK |
| Pentasa Sachet 2g prolonged release granules       | DK/H/0140/002 | PL 03194/0102    | FERRING PHARMACEUTICALS LTD. | UK |
| Pentasa 2 g κοκκία παρατεταμένης αποδέσμευσης      | DK/H/0140/002 | 22417/22.03.2018 | FERRING HELLAS MEPE          | GR |
| Pentasa 500 mg ilgstošās darbības tabletes         | not available | 98-0118          | FERRING GMBH                 | LV |
| PENTASA 1g compresse a rilascio modificato         | not available | 027130107        | FERRING S.P.A.               | IT |
| PENTASA® 500 mg, comprimé                          | not available | 3400933278717    | FERRING S.A.S.               | FR |
| PENTASA® 500 mg, comprimé                          | not available | 3400933278885    | FERRING S.A.S.               | FR |
| PENTASA 500 mg Retardtabletten                     | not available | 16944.00.01      | FERRING GMBH                 | DE |
| Pentasa Sachet 1 g granulés à libération prolongée | not available | 0349/08100013    | FERRING N.V.                 | LU |
| Pentasa Sachet 2 g granulés à libération prolongée | not available | 0349/10040049    | FERRING N.V.                 | LU |

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|--|---------------|---------------|--------------------|----|
| PENTASA 500 mg<br>compresse a rilascio<br>modificato | not available | 027130071     | FERRING S.P.A.     | IT |
| Pentasa Sachet 1 g<br>Retardgranulat                 | not available | 0349/08100013 | FERRING N.V.       | LU |
| Pentasa Sachet 2 g<br>Retardgranulat                 | not available | 0349/10040049 | FERRING N.V.       | LU |
| Asacol 1 g<br>rektalsuspension                       | not available | 13251         | TILLOTTS PHARMA AB | SE |
| PENTASA 1g compresse<br>a rilascio modificato        | not available | 027130107     | FERRING S.P.A.     | IT |
| PENTASA® 500 mg,<br>comprimé                         | not available | 3400933278717 | FERRING S.A.S.     | FR |
| PENTASA® 500 mg,<br>comprimé                         | not available | 3400933278885 | FERRING S.A.S.     | FR |
| PENTASA 500 mg<br>Retardtabletten                    | not available | 16944.00.01   | FERRING GMBH       | DE |
| PENTASA 500 mg<br>compresse a rilascio<br>modificato | not available | 027130071     | FERRING S.P.A.     | IT |
| ASACOL 400 mg<br>compresse<br>gastroresistenti       | not available | 026416014     | GIULIANI SPA       | IT |

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|--|---------------|-----------|--------------|----|
| ASACOL 400 mg<br>compresse<br>gastroresistenti | not available | 026416329 | GIULIANI SPA | IT |
| ASACOL 800 mg<br>compresse<br>gastroresistenti | not available | 026416242 | GIULIANI SPA | IT |
| ASACOL 800 mg<br>compresse<br>gastroresistenti | not available | 026416317 | GIULIANI SPA | IT |
| ASACOL 800 mg<br>compresse<br>gastroresistenti | not available | 026416293 | GIULIANI SPA | IT |
| ASACOL 400 mg capsule<br>a rilascio modificato | not available | 026416255 | GIULIANI SPA | IT |
| ASACOL 500 mg<br>supposte                      | not available | 026416127 | GIULIANI SPA | IT |
| ASACOL 500 mg<br>supposte                      | not available | 026416139 | GIULIANI SPA | IT |
| ASACOL 1g supposte                             | not available | 026416305 | GIULIANI SPA | IT |
| ASACOL 2 g/50 ml<br>sospensione rettale        | not available | 026416141 | GIULIANI SPA | IT |
| ASACOL 4 g/100 ml<br>sospensione rettale       | not available | 026416154 | GIULIANI SPA | IT |
| ASACOL 4 g/50 ml<br>sospensione rettale        | not available | 026416166 | GIULIANI SPA | IT |

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|--|---------------|-----------------|----------------------|----|
| ASACOL 2 g granulato per sospensione rettale | not available | 026416091       | GIULIANI SPA         | IT |
| ASACOL 2 g schiuma rettale                   | not available | 026416216       | GIULIANI SPA         | IT |
| ASACOL 4 g schiuma rettale                   | not available | 026416230       | GIULIANI SPA         | IT |
| ASACOL 1 g schiuma rettale                   | not available | 026416267       | GIULIANI SPA         | IT |
| ASACOL 1 g schiuma rettale                   | not available | 026416279       | GIULIANI SPA         | IT |
| PENTASA® 500 mg, comprimé                    | not available | 3400933278717   | FERRING S.A.S.       | FR |
| PENTASA® 500 mg, comprimé                    | not available | 3400933278885   | FERRING S.A.S.       | FR |
| PENTASA 500 mg Retardtabletten               | not available | 16944.00.01     | FERRING GMBH         | DE |
| Pentasa 500 mg Prolonged-release Tablets     | not available | PA 1009/006/005 | FERRING IRELAND LTD. | IE |
| PENTASA® 500 mg, comprimé                    | not available | 3400933278717   | FERRING S.A.S.       | FR |
| PENTASA® 500 mg, comprimé                    | not available | 3400933278885   | FERRING S.A.S.       | FR |



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|---|---------------|---------------|-----------------------|----|
| PENTASA 500 mg<br>Retardtabletten                                     | not available | 16944.00.01   | FERRING GMBH          | DE |
| PENTASA 1 g granulato a<br>rilascio prolungato                        | not available | 027130083     | FERRING S.P.A.        | IT |
| PENTASA® 500 mg,<br>comprimé  | not available | 3400933278717 | FERRING S.A.S.        | FR |
| PENTASA® 500 mg,<br>comprimé  | not available | 3400933278885 | FERRING S.A.S.        | FR |
| PENTASA 1000 mg<br>Rektalsuspension                                   | not available | 13913.00.00   | FERRING GMBH          | DE |
| Claversal® Micropellets<br>1,5 g,<br>magensaftresistentes<br>Granulat | not available | 42197.00.01   | RECORDATI PHARMA GMBH | DE |
| Claversal®<br>Rektalschaum 1 g  | not available | 42197.00.00   | RECORDATI PHARMA GMBH | DE |
| ASACOL 400 tablet,<br>maagsapresistente<br>tabletten 400 mg           | not available | RVG 11737     | TAKEDA NEDERLAND B.V. | NL |
| ASACOL 800 tablet,<br>maagsapresistente<br>tabletten 800 mg           | not available | RVG 18636     | TAKEDA NEDERLAND B.V. | NL |
| PENTASA, 1 g, tabletki o<br>przedłużonym uwalnianiu                   | not available | 20099         | FERRING GMBH          | PL |

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|--|---------------|-----------------------|----------------------|----|
| PENTASA, 500 mg, tabletki o przedłużonym uwalnianiu    | not available | R/6621                | FERRING GMBH         | PL |
| Asacol® 400 mg gastrorezistentne tablete               | not available | H/04/00214/001        | TILLOTTS PHARMA GMBH | SI |
| Pentasa vrećice 2 g granule s produljenim oslobađanjem | not available | UP/I-530-09/12-01/601 | FERRING GMBH         | HR |
| Asacol 500 mg suppositorier                            | not available | 12093                 | TILLOTTS PHARMA AB   | SE |
| ASACOL čípky   | not available | 29/619/99-C           | TILLOTTS PHARMA GMBH | CZ |
| PENTASA 1g Supositorios                                | not available | 60.151                | FERRING S.A.U.       | ES |
| Pentasa 500 mg ilgstošās darbības tabletes             | not available | 98-0118               | FERRING GMBH         | LV |
| PENTASA 1g compresse a rilascio modificato             | not available | 027130107             | FERRING S.P.A.       | IT |
| PENTASA® 500 mg, comprimé                              | not available | 3400933278717         | FERRING S.A.S.       | FR |
| PENTASA® 500 mg, comprimé                              | not available | 3400933278885         | FERRING S.A.S.       | FR |
| PENTASA 500 mg Retardtabletten                         | not available | 16944.00.01           | FERRING GMBH         | DE |

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|---|---------------|------------------|----------------------|----|
| PENTASA 500 mg<br>compresse a rilascio<br>modificato    | not available | 027130071        | FERRING S.P.A.       | IT |
| PENTASA 1 g rektální<br>suspenze                        | not available | 29/183/00-C      | FERRING LÉCIVA A.S.  | CZ |
| Pentasa 1 g/100 ml<br>suspensie voor rectaal<br>gebruik | not available | BE150683         | FERRING N.V.         | BE |
| Pentasa 1 g/100 ml<br>suspension rectale                | not available | BE150683         | FERRING N.V.         | BE |
| Asacolón 500 mg<br>Suppositories                        | not available | PA2018/001/003   | TILLOTTS PHARMA GMBH | IE |
| Pentasa 500 mg ilgstošās<br>darbības tabletes           | not available | 98-0118          | FERRING GMBH         | LV |
| PENTASA 1g compresse<br>a rilascio modificato           | not available | 027130107        | FERRING S.P.A.       | IT |
| PENTASA® 500 mg,<br>comprimé                            | not available | 3400933278717    | FERRING S.A.S.       | FR |
| PENTASA® 500 mg,<br>comprimé                            | not available | 3400933278885    | FERRING S.A.S.       | FR |
| PENTASA 500 mg<br>Retardtabletten                       | not available | 16944.00.01      | FERRING GMBH         | DE |
| PENTASA 500 mg<br>pailginto atpalaidavimo<br>tabletės   | not available | LT/1/96/1965/006 | FERRING GMBH         | LT |

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|--|---------------|---------------|----------------|----|
| PENTASA 500 mg compresse a rilascio modificato | not available | 027130071     | FERRING S.P.A. | IT |
| Pentasa 500 mg ilgstošās darbības tabletes     | not available | 98-0118       | FERRING GMBH   | LV |
| PENTASA 1g compresse a rilascio modificato     | not available | 027130107     | FERRING S.P.A. | IT |
| PENTASA® 500 mg, comprimé                      | not available | 3400933278717 | FERRING S.A.S. | FR |
| PENTASA® 500 mg, comprimé                      | not available | 3400933278885 | FERRING S.A.S. | FR |
| PENTASA 500 mg Retardtabletten                 | not available | 16944.00.01   | FERRING GMBH   | DE |
| Pentasa 1 g suppositoires                      | not available | 0349/09050317 | FERRING N.V.   | LU |
| PENTASA 500 mg compresse a rilascio modificato | not available | 027130071     | FERRING S.P.A. | IT |
| Pentasa 1 g Zäpfchen                           | not available | 0349/09050317 | FERRING N.V.   | LU |
| Pentasa 500 mg ilgstošās darbības tabletes     | not available | 98-0118       | FERRING GMBH   | LV |
| PENTASA 1g compresse a rilascio modificato     | not available | 027130107     | FERRING S.P.A. | IT |

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|--|---------------|-----------------|----------------------|----|
| PENTASA® 500 mg, comprimé                          | not available | 3400933278717   | FERRING S.A.S.       | FR |
| PENTASA® 500 mg, comprimé                          | not available | 3400933278885   | FERRING S.A.S.       | FR |
| PENTASA 500 mg Retardtabletten                     | not available | 16944.00.01     | FERRING GMBH         | DE |
| PENTASA 500 mg compresse a rilascio modificato     | not available | 027130071       | FERRING S.P.A.       | IT |
| Pentasa Sachet 4 g granulés à libération prolongée | not available | 2018010044      | FERRING N.V.         | LU |
| Pentasa Sachet 4 g Retardgranulat                  | not available | 2018010044      | FERRING N.V.         | LU |
| PENTASA® 500 mg, comprimé                          | not available | 3400933278717   | FERRING S.A.S.       | FR |
| PENTASA® 500 mg, comprimé                          | not available | 3400933278885   | FERRING S.A.S.       | FR |
| PENTASA 500 mg Retardtabletten                     | not available | 16944.00.01     | FERRING GMBH         | DE |
| Pentasa 1g Suppositories                           | not available | PA 1009/006/002 | FERRING IRELAND LTD. | IE |
| PENTACOL 2 g schiuma rettale                       | not available | 026925089       | SOFAR S.P.A.         | IT |

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|--|---------------|-----------------------|----------------------|----|
| PENTACOL 4 g schiuma rettale                           | not available | 026925077             | SOFAR S.P.A.         | IT |
| PENTACOL 2 g schiuma rettale                           | not available | 026925127             | SOFAR S.P.A.         | IT |
| PENTACOL 4 g schiuma rettale                           | not available | 026925115             | SOFAR S.P.A.         | IT |
| PENTASA® 1g, suppositoire                              | not available | 3400933502782         | FERRING S.A.S.       | FR |
| PENTASA® 1g, suppositoire                              | not available | 3400933502843         | FERRING S.A.S.       | FR |
| PENTASA 1 g, suppositoire                              | not available | 34009 301 817 1 3     | FERRING S.A.S.       | FR |
| ASACOL 400 mg enterotabletter                          | not available | 11344                 | TILLOTTS PHARMA AB   | FI |
| ASACOL 400 mg enterotabletit                           | not available | 11344                 | TILLOTTS PHARMA AB   | FI |
| ASACOL ENEMA 4 G rektální suspenze                     | not available | 29/174/95-C           | TILLOTTS PHARMA GMBH | CZ |
| Pentasa vrećice 2 g granule s produljenim oslobađanjem | not available | UP/I-530-09/12-01/601 | FERRING GMBH         | HR |
| Пентаза 1 g супозитории                                | not available | 9900188               | FERRING GMBH         | BG |

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|--|---------------|---------------|------------------------------|----|
| Pentasa Sachet 2g granules prodlouženým uvolnováním          | not available | 29/669/07-C   | FERRING LÉCIVA A.S.          | CZ |
| Asacol 800 mg enterosolventní tablety                        | not available | 29/091/08-C   | TILLOTTS PHARMA GMBH         | CZ |
| Colitofalk 250 mg zetpillen                                  | not available | BE132273      | DR. FALK PHARMA BENELUX B.V. | BE |
| Colitofalk 250 mg suppositoires                              | not available | BE132273      | DR. FALK PHARMA BENELUX B.V. | BE |
| PENTASA® 500 mg, comprimé                                    | not available | 3400933278717 | FERRING S.A.S.               | FR |
| PENTASA® 500 mg, comprimé                                    | not available | 3400933278885 | FERRING S.A.S.               | FR |
| Asacol 400 mg enterotabletter                                | not available | 11580         | TILLOTTS PHARMA AB           | SE |
| Pentasa 1 g, toimeainet prolongeeritult vabastavad graanulid | not available | 659709        | FERRING GMBH                 | EE |
| Pentasa 2 g, toimeainet prolongeeritult vabastavad graanulid | not available | 659809        | FERRING GMBH                 | EE |
| Pentasa Sachet, depotgranulat, enkeltdosisbeholder           | not available | 55370         | FERRING LÆGEMIDLER A/S       | DK |

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|---|---------------|---------------|------------------------|----|
| Pentasa, rektalvæske, suspension, enkeltdosisbeholder     | not available | 11718         | FERRING LÆGEMIDLER A/S | DK |
| PENTASA čípky   | not available | 29/009/95 - C | FERRING LÉCIVA A.S.    | CZ |
| Pentasa Sachet, depotgranulat, enkeltdosisbeholder        | not available | 16895         | FERRING LÆGEMIDLER A/S | DK |
| Pentasa Sachet, depotgranulat, enkeltdosisbeholder        | not available | 36822         | FERRING LÆGEMIDLER A/S | DK |
| PENTASA čípky   | not available | 29/009/95 - C | FERRING LÉCIVA A.S.    | CZ |
| Pentasa, suppositorier                                    | not available | 13943         | FERRING LÆGEMIDLER A/S | DK |
| Claversal® 250 mg Zäpfchen                                | not available | 5697.00.00    | RECORDATI PHARMA GMBH  | DE |
| Pentasa Prolong 500 mg tablety s prodlouženým uvolňováním | not available | 29/014/95 - C | FERRING LÉCIVA A.S.    | CZ |
| PENTASA 1g compresse a rilascio modificato                | not available | 027130107     | FERRING S.P.A.         | IT |
| PENTASA® 500 mg, comprimé                                 | not available | 3400933278717 | FERRING S.A.S.         | FR |
| PENTASA® 500 mg, comprimé                                 | not available | 3400933278885 | FERRING S.A.S.         | FR |



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|---|---------------|-------------------|------------------------------------|----|
| PENTASA 500 mg<br>Retardtabletten                     | not available | 16944.00.01       | FERRING GMBH                       | DE |
| Pentasa 1 g ilgstošās<br>darbības granulas            | not available | 10-0562           | FERRING GMBH                       | LV |
| Pentasa 2 g ilgstošās<br>darbības granulas            | not available | 10-0563           | FERRING GMBH                       | LV |
| PENTASA 500 mg<br>compresse a rilascio<br>modificato  | not available | 027130071         | FERRING S.P.A.                     | IT |
| Pentasa 1 g, tabletten<br>met verlengde afgifte       | not available | RVG 105712        | FERRING B.V.                       | NL |
| Pentasa 500 mg,<br>tabletten met verlengde<br>afgifte | not available | RVG 14797         | FERRING B.V.                       | NL |
| Pentasa-Klyisma                                       | not available | 1-19907           | FERRING ARZNEIMITTEL<br>GES.M.B.H. | AT |
| PENTASA® 1g,<br>comprimé                              | not available | 34009 498 584 3 9 | FERRING S.A.S.                     | FR |
| Asacol® 800 mg<br>gastrorezistentne tablete           | not available | H/04/00214/002    | TILLOTTS PHARMA GMBH               | SI |
| Asacol® 800 mg<br>gastrorezistentne tablete           | not available | H/04/00214/003    | TILLOTTS PHARMA GMBH               | SI |

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|--|---------------|--------------|---|----|
| Pentasa 4000 mg<br>Granulato de libertação<br>modificada               | not available | 5757935      | FERRING PORTUGUESA –<br>PRODUTOS<br>FARMACÊUTICOS,<br>SOCIEDADE UNIPessoal,<br>LDA. | PT |
| Pentasa 1000 mg<br>supozitoare   | not available | 8670/2016/01 | FERRING GMBH  | RO |
| Pentasa 1g suppositorier   | not available | 16690        | FERRING LÄKEMEDEL AB  | SE |
| ASALEX 800 mg<br>comprese<br>gastroresistenti a rilascio<br>prolungato | not available | 027122124    | CHIESI FARMACEUTICI<br>S.P.A.   | IT |
| ASALEX 400 mg<br>comprese<br>gastroresistenti a rilascio<br>prolungato | not available | 027122100    | CHIESI FARMACEUTICI<br>S.P.A.   | IT |
| ASALEX 2 g/60 ml<br>sospensione rettale                                | not available | 027122062    | CHIESI FARMACEUTICI<br>S.P.A.   | IT |
| ASALEX 4 g/60 ml<br>sospensione rettale                                | not available | 027122098    | CHIESI FARMACEUTICI<br>S.P.A.   | IT |
| ASALEX 1,5 g granulato<br>per sospensione rettale                      | not available | 027122112    | CHIESI FARMACEUTICI<br>S.P.A.   | IT |
| ASACOL 500 mg<br>suppositorier   | not available | 11562        | TILLOTTS PHARMA AB  | FI |

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| ASACOL 500 mg peräpuikko   | not available | 11562             | TILLOTTS PHARMA AB  | FI |
| Pentasa 1 g suspenzija za rektum                                     | not available | HR-H-296920131    | FERRING GMBH  | HR |
| FIVASA 1600 mg, comprimé gastro-résistant                            | not available | 34009 301 998 6 2 | TILLOTTS PHARMA GMBH  | FR |
| FIVASA 1600 mg, comprimé gastro-résistant                            | not available | 34009 301 998 7 9 | TILLOTTS PHARMA GMBH  | FR |
| FIVASA 1600 mg, comprimé gastro-résistant                            | not available | 34009 301 998 8 6 | TILLOTTS PHARMA GMBH  | FR |
| Pentasa Slow release tablets 500 mg tablety s predlženým uvolnovaním | not available | 29/0426/95-S      | FERRING LÉCIVA A.S.   | SK |
| Салофалк 500 mg супозитории  | not available | 9600068           | DR FALK PHARMA GMBH   | BG |
| Pentasa 1g Granulado de libertação modificada                        | not available | 3292588           | FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA. | PT |

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| Pentasa 1g Granulado de libertação modificada      | not available | 3292687          | FERRING PORTUGUESA –<br>PRODUTOS<br>FARMACÊUTICOS,<br>SOCIEDADE UNIPESSOAL,<br>LDA. | PT |
| Pentasa 2000 mg Granulado de libertação modificada | not available | 5731542          | FERRING PORTUGUESA –<br>PRODUTOS<br>FARMACÊUTICOS,<br>SOCIEDADE UNIPESSOAL,<br>LDA. | PT |
| PENTASA® 500 mg, comprimé                          | not available | 3400933278717    | FERRING S.A.S.  | FR |
| PENTASA® 500 mg, comprimé                          | not available | 3400933278885    | FERRING S.A.S.  | FR |
| PENTASA 500 mg Retardtabletten                     | not available | 16944.00.01      | FERRING GMBH  | DE |
| Pentasa 500 mg forðatöflur                         | not available | 900151           | FERRING LÆGEMIDLER A/S  | IS |
| Pentasa 1 g forðatöflur                            | not available | IS/1/10/135/01   | FERRING LÆGEMIDLER A/S  | IS |
| Asacol, Υπόθετα, 500 mg                            | not available | 30723/03-05-2012 | ANGELINI PHARMA HELLAS<br>S.A.  | GR |
| Salofalk 500mg, gastro-resistant tablets           | not available | 13056            | DR FALK PHARMA GMBH   | CY |

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| Pentasa 1 g<br>végbélszuszpenzió                           | not available | OGYI-T- 4798/03 | FERRING MAGYARORSZÁG<br>GYÓGYSZERKERESKEDELMI<br>KFT. | HU |
| Asacol 800 mg<br>enterotabletter                           | not available | 17894           | TILLOTTS PHARMA AB                                    | SE |
| Pentasa 1000 mg<br>supozitoare                             | not available | 8670/2016/01    | FERRING GMBH  | RO |
| Pentasa Compact 4 g,<br>granulaat met verlengde<br>afgifte | not available | RVG 114015      | FERRING B.V.  | NL |
| Pentasa Compact 1 g,<br>granulaat met verlengde<br>afgifte | not available | RVG 18706       | FERRING B.V.  | NL |
| Pentasa Compact 2 g,<br>granulaat met verlengde<br>afgifte | not available | RVG 31379       | FERRING B.V.  | NL |
| Pentasa retard 1 g -<br>Tabletten                          | not available | 1-31050         | FERRING ARZNEIMITTEL<br>GES.M.B.H.                    | AT |
| Pentasa retard 500 mg -<br>Tabletten                       | not available | 1-20047         | FERRING ARZNEIMITTEL<br>GES.M.B.H.                    | AT |
| LIXACOL 400 mg<br>comprimidos<br>gastroresistentes         | not available | 57726           | TILLOTTS PHARMA SPAIN<br>S.A.                         | ES |
| Pentasa 500 mg ilgstošās<br>darbības tabletes              | not available | 98-0118         | FERRING GMBH  | LV |

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| PENTASA 1g compresse a rilascio modificato   | not available | 027130107        | FERRING S.P.A. | IT |
| PENTASA® 500 mg, comprimé                    | not available | 3400933278717    | FERRING S.A.S. | FR |
| PENTASA® 500 mg, comprimé                    | not available | 3400933278885    | FERRING S.A.S. | FR |
| PENTASA 500 mg Retardtabletten               | not available | 16944.00.01      | FERRING GMBH   | DE |
| PENTASA 1 g pailginto atpalaidavimo granulės | not available | LT/1/96/1965/001 | FERRING GMBH   | LT |
| PENTASA 1 g pailginto atpalaidavimo granulės | not available | LT/1/96/1965/002 | FERRING GMBH   | LT |
| PENTASA 1 g pailginto atpalaidavimo granulės | not available | LT/1/96/1965/008 | FERRING GMBH   | LT |
| PENTASA 1 g pailginto atpalaidavimo granulės | not available | LT/1/96/1965/003 | FERRING GMBH   | LT |
| PENTASA 2 g pailginto atpalaidavimo granulės | not available | LT/1/96/1965/004 | FERRING GMBH   | LT |
| PENTASA 2 g pailginto atpalaidavimo granulės | not available | LT/1/96/1965/005 | FERRING GMBH   | LT |
| PENTASA 2 g pailginto atpalaidavimo granulės | not available | LT/1/96/1965/009 | FERRING GMBH   | LT |

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| PENTASA 500 mg<br>compresse a rilascio<br>modificato | not available | 027130071        | FERRING S.P.A.                  | IT |
| ASACOL 1 g rektalvätska                              | not available | 12432            | TILLOTTS PHARMA AB              | FI |
| ASACOL 1 g peräruiske                                | not available | 12432            | TILLOTTS PHARMA AB              | FI |
| Colitofalk 2 g suspensie<br>voor rectaal gebruik     | not available | BE157272         | DR. FALK PHARMA BENELUX<br>B.V. | BE |
| Colitofalk 2 g suspension<br>rectale                 | not available | BE157272         | DR. FALK PHARMA BENELUX<br>B.V. | BE |
| Asacol 4 g / SINGLE<br>DOSE, Ορθικό εναιώρημα        | not available | 30723/03-05-2012 | ANGELINI PHARMA HELLAS<br>S.A.  | GR |
| PENTASA® 500 mg,<br>comprimé                         | not available | 3400933278717    | FERRING S.A.S.                  | FR |
| PENTASA® 500 mg,<br>comprimé                         | not available | 3400933278885    | FERRING S.A.S.                  | FR |
| PENTASA 500 mg<br>Retardtabletten                    | not available | 16944.00.01      | FERRING GMBH                    | DE |
| Pentasa 10 mg/ml Rectal<br>Suspension                | not available | PA 1009/006/003  | FERRING IRELAND LTD.            | IE |
| Pentasa 2 g granule cu<br>eliberare prelungită       | not available | 7178/2014/01     | FERRING GMBH                    | RO |
| Pentasa 2 g granule cu<br>eliberare prelungită       | not available | 7178/2014/02     | FERRING GMBH                    | RO |

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| Pentasa 1 g rektalsuspension                    | not available | 14430           | FERRING LÄKEMEDEL AB                            | SE |
| Pentasa 4 g retard granulátum                   | not available | OGYI-T- 4798/06 | FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDELMI KFT. | HU |
| Pentasa 2 g retard granulátum                   | not available | OGYI-T- 4798/04 | FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDELMI KFT. | HU |
| Colitofalk 250 mg maagsapersistente tabletten   | not available | BE141364        | DR. FALK PHARMA BENELUX B.V.                    | BE |
| Colitofalk 250 mg comprimés gastro-résistants   | not available | BE141364        | DR. FALK PHARMA BENELUX B.V.                    | BE |
| Pentasa 1 g comprimés à libération prolongée    | not available | BE477306        | FERRING N.V.                                    | BE |
| Pentasa 1 g tabletten met verlengde afgifte     | not available | BE477306        | FERRING N.V.                                    | BE |
| Pentasa 500 mg comprimés à libération prolongée | not available | BE156055        | FERRING N.V.                                    | BE |
| Pentasa 500 mg comprimés à libération prolongée | not available | BE230991        | FERRING N.V.                                    | BE |



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| Pentasa 500 mg<br>tabletten met verlengde<br>afgifte                       | not available | BE156055  | FERRING N.V. | BE |
| Pentasa 500 mg<br>tabletten met verlengde<br>afgifte                       | not available | BE230991  | FERRING N.V. | BE |
| Pentasa 500 mg<br>Retardtabletten  | not available | BE156055  | FERRING N.V. | BE |
| Pentasa 500 mg<br>Retardtabletten  | not available | BE230991  | FERRING N.V. | BE |
| Pentasa 1 g<br>Retardtabletten   | not available | BE477306  | FERRING N.V. | BE |
| PENTACOL 1200 mg<br>compresse<br>gastroresistenti a rilascio<br>modificato | not available | 026925228 | SOFAR S.P.A. | IT |
| PENTACOL 1200 mg<br>compresse<br>gastroresistenti a rilascio<br>modificato | not available | 026925230 | SOFAR S.P.A. | IT |
| PENTACOL 400 mg<br>compresse<br>gastroresistenti a rilascio<br>modificato  | not available | 026925040 | SOFAR S.P.A. | IT |

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| PENTACOL 800 mg<br>compresse<br>gastroresistenti a rilascio<br>modificato | not available | 026925166 | SOFAR S.P.A.        | IT |
| PENTACOL 800 mg<br>compresse<br>gastroresistenti a rilascio<br>modificato | not available | 026925053 | SOFAR S.P.A.        | IT |
| PENTACOL 800 mg<br>compresse<br>gastroresistenti a rilascio<br>modificato | not available | 026925178 | SOFAR S.P.A.        | IT |
| PENTASA® 1 g<br>depotgranulat   | not available | 23857     | FERRING LÄÄKKEET OY | FI |
| PENTASA® 2 g<br>depotgranulat   | not available | 23858     | FERRING LÄÄKKEET OY | FI |
| PENTASA 1 g<br>depotrakeet  | not available | 23857     | FERRING LÄÄKKEET OY | FI |
| PENTASA 2 g<br>depotrakeet  | not available | 23858     | FERRING LÄÄKKEET OY | FI |
| PENTASA 4 g<br>depotrakeet  | not available | 34347     | FERRING LÄÄKKEET OY | FI |
| PENTASA® 4 g<br>depotgranulat   | not available | 34347     | FERRING LÄÄKKEET OY | FI |

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| Pentasa retard 1 g - Granulat                  | not available | 1-22009       | FERRING ARZNEIMITTEL GES.M.B.H. | AT |
| Pentasa retard 2 g - Granulat                  | not available | 1-26559       | FERRING ARZNEIMITTEL GES.M.B.H. | AT |
| Pentasa 500 mg ilgstošās darbības tabletes     | not available | 98-0118       | FERRING GMBH                    | LV |
| PENTASA 1g compresse a rilascio modificato     | not available | 027130107     | FERRING S.P.A.                  | IT |
| PENTASA® 500 mg, comprimé                      | not available | 3400933278717 | FERRING S.A.S.                  | FR |
| PENTASA® 500 mg, comprimé                      | not available | 3400933278885 | FERRING S.A.S.                  | FR |
| PENTASA 500 mg Retardtabletten                 | not available | 16944.00.01   | FERRING GMBH                    | DE |
| Pentasa 1 g/100 ml suspension rectale          | not available | 2009050315    | FERRING N.V.                    | LU |
| PENTASA 500 mg compresse a rilascio modificato | not available | 027130071     | FERRING S.P.A.                  | IT |
| Pentasa 1 g/100 ml Rektalsuspension            | not available | 2009050315    | FERRING N.V.                    | LU |
| Pentasa® Slow Release Tablets 500mg            | not available | PL 3194/0044  | FERRING PHARMACEUTICALS LTD.    | UK |

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| PENTASA® Slow Release Tablets 1g              | not available                 | PL 3194/0108   | FERRING PHARMACEUTICALS LTD. | UK |
| Asacolone 400mg Gastro-resistant Tablets      | not available                 | PA2018/001/001 | TILLOTTS PHARMA GMBH         | IE |
| Salofalk 250mg gastro-resistant tablets       | not available                 | MA 026/00101   | DR FALK PHARMA GMBH          | MT |
| Pentasa 2g granulado de liberación prolongada | not available                 | 77.668         | FERRING S.A.U.               | ES |
| Norasa 500 mg magensaftresistente Tabletten   | DE/H/6117/001 (UK/H/4008/001) | 2202830.00.00  | DISPHAR INTERNATIONAL B.V.   | DE |
| Claversal® 4 g/60 g Klysmen, Rektalsuspension | not available                 | 40157.00.00    | RECORDATI PHARMA GMBH        | DE |
| PENTASA® 500 mg, comprimé                     | not available                 | 3400933278717  | FERRING S.A.S.               | FR |
| PENTASA® 500 mg, comprimé                     | not available                 | 3400933278885  | FERRING S.A.S.               | FR |
| PENTASA 1000 mg Zäpfchen                      | not available                 | 16944.00.02    | FERRING GMBH                 | DE |
| PENTASA® 500 mg, comprimé                     | not available                 | 3400933278717  | FERRING S.A.S.               | FR |
| PENTASA® 500 mg, comprimé                     | not available                 | 3400933278885  | FERRING S.A.S.               | FR |

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| PENTASA 500 mg<br>Retardtabletten                    | not available | 16944.00.01    | FERRING GMBH  | DE |
| Pentasa 1 g<br>endaþarmsstílar.                      | not available | 900152 (IS)    | FERRING LÆGEMIDLER A/S                              | IS |
| Pentasa Sachet 4 g<br>forðakyrni                     | not available | IS/1/16/037/01 | FERRING LÆGEMIDLER A/S                              | IS |
| Pentasa Sachet 1 g<br>forðakyrni                     | not available | 940305         | FERRING LÆGEMIDLER A/S                              | IS |
| Pentasa Sachet 2 g<br>forðakyrni                     | not available | IS/1/05/104/01 | FERRING LÆGEMIDLER A/S                              | IS |
| ASAVIXIN 500 mg<br>COMPRESSE RIVESTITE               | not available | 035356017      | MEDA PHARMA S.P.A.                                  | IT |
| ASAVIXIN 10% GEL<br>RETTALE                          | not available | 035356056      | MEDA PHARMA S.P.A.                                  | IT |
| PENTASA 1g Supositorios                              | not available | 60.151         | FERRING S.A.U.                                      | ES |
| Colitofalk 500 mg<br>comprimés gastro-<br>résistants | not available | BE156597       | DR. FALK PHARMA BENELUX<br>B.V.                     | BE |
| Colitofalk 500 mg<br>maagsapresistente<br>tabletten  | not available | BE156597       | DR. FALK PHARMA BENELUX<br>B.V.                     | BE |
| Asacol 800mg MR<br>Tablets                           | not available | PL 45496/0002  | ALLERGAN<br>PHARMACEUTICAL<br>INTERNATIONAL LIMITED | UK |

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| ASACOL500 mg<br>Suppositories                           | not available | 19626        | TILLOTTS PHARMA GMBH            | CY |
| PENTASA® 1 g<br>depottablett                            | not available | 27787        | FERRING LÄÄKKEET OY             | FI |
| PENTASA® 500 mg<br>depottablett                         | not available | 10992        | FERRING LÄÄKKEET OY             | FI |
| Colitofalk 500 mg<br>comprimés gastro-<br>résistants    | not available | 198211051169 | DR. FALK PHARMA BENELUX<br>B.V. | LU |
| Pentasa 500 mg<br>comprimate cu eliberare<br>prelungită | not available | 9996/2017/01 | FERRING GMBH                    | RO |
| PENTASA 1 g<br>comprimate cu eliberare<br>prelungită    | not available | 4480/2012/01 | FERRING GMBH                    | RO |
| PENTASA® 1 g<br>suppositorium                           | not available | 10993        | FERRING LÄÄKKEET OY             | FI |
| PENTASA 1 g peräpuikko                                  | not available | 10993        | FERRING LÄÄKKEET OY             | FI |
| Pentasa 1 g, tabletten<br>met verlengde afgifte         | not available | RVG 105712   | FERRING B.V.                    | NL |
| Pentasa 500 mg,<br>tabletten met verlengde<br>afgifte   | not available | RVG 14797    | FERRING B.V.                    | NL |
| Colitofalk 4 g suspension<br>rectale                    | not available | BE145275     | DR. FALK PHARMA BENELUX<br>B.V. | BE |

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| Colitofalk 4 g suspensie voor rectaal gebruik                  | not available | BE145275      | DR. FALK PHARMA BENELUX B.V. | BE |
| Mesalazin Orion 500 mg enterotabletter                         | ES/H/0587/001 | 58289         | FAES FARMA, S.A.             | SE |
| Mesalazin "Orion", enterotabletter                             | ES/H/0587/001 | 61716         | FAES FARMA, S.A.             | DK |
| Mesalazin Orion 500 mg enterotablett                           | ES/H/0587/001 | 18-12463      | FAES FARMA, S.A.             | NO |
| Mesalazin Orion 500 mg enterotabletit                          | ES/H/0587/001 | 36387         | FAES FARMA, S.A.             | FI |
| Mesalazin Orion 500 mg enterotabletter                         | ES/H/0587/001 | 36387         | FAES FARMA, S.A.             | FI |
| Azzavix 500 mg comprimidos gastrorresistentes                  | ES/H/0587/001 | 84676         | FAES FARMA, S.A.             | ES |
| Mecolazine 500 mg gastro-resistant tablets.                    | ES/H/0587/001 | MA1278/00101  | FAES FARMA, S.A.             | MT |
| Salofalk 500mg gastro-resistant tablets                        | not available | MA 026/00102  | DR FALK PHARMA GMBH          | MT |
| PENTASA čípky  | not available | 29/009/95 - C | FERRING LÉCIVA A.S.          | CZ |
| Pentasa, 500 mg toimeainet prolongeeritult vabastavad tabletid | not available | 145496        | FERRING GMBH                 | EE |

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| Pentasa® Suppositories<br>1g   | not available | PL 3194/0045      | FERRING<br>PHARMACEUTICALS LTD. | UK |
| Mesavancol 1200mg<br>maagsapersistent,<br>tabletten met een<br>verlengde afgifte | NL/H/0733/001 | RVG: 33597        | GIULIANI SPA                    | NL |
| Mesavancol 1200 mg<br>compresse<br>gastroresistenti, a<br>rilascio prolungato    | NL/H/0733/001 | 037734011         | GIULIANI SPA                    | IT |
| Mesavancol 1200 mg<br>compresse<br>gastroresistenti, a<br>rilascio prolungato    | NL/H/0733/001 | 037734023         | GIULIANI SPA                    | IT |
| PENTASA 1 g, granulés<br>en sachet   | not available | 3400934748622     | FERRING S.A.S.                  | FR |
| PENTASA 1 g, granulés<br>en sachet   | not available | 3400934424601     | FERRING S.A.S.                  | FR |
| PENTASA 1 g, granulés<br>en sachet   | not available | 3400934424779     | FERRING S.A.S.                  | FR |
| PENTASA 2 g, granulés<br>en sachet-dose  | not available | 3400936758797     | FERRING S.A.S.                  | FR |
| PENTASA 1g, granulés<br>en sachet.   | not available | 34009 301 817 2 0 | FERRING S.A.S.                  | FR |



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| PENTASA 4 g, granulés en sachet                        | not available | 34009 301 927 8 8 | FERRING S.A.S.              | FR |
| PENTASA 4 g, granulés en sachet                        | not available | 34009 301 927 9 5 | FERRING S.A.S.              | FR |
| PENTASA 4 g, granulés en sachet                        | not available | 34009 301 928 0 1 | FERRING S.A.S.              | FR |
| PENTASA 4 g, granulés en sachet                        | not available | 34009 301 928 1 8 | FERRING S.A.S.              | FR |
| Mesalazine Disphar 750 mg, maagsapresistente tabletten | not available | RVG 114896        | DISPHAR INTERNATIONAL B.V.  | NL |
| Asacol 800 mg, Γαστρανθηεκτικά δισκία                  | not available | 30723/03-05-2012  | ANGELINI PHARMA HELLAS S.A. | GR |
| Pentasa 500 mg ilgstošās darbības tabletes             | not available | 98-0118           | FERRING GMBH                | LV |
| PENTASA 1g compresse a rilascio modificato             | not available | 027130107         | FERRING S.P.A.              | IT |
| PENTASA® 500 mg, comprimé                              | not available | 3400933278717     | FERRING S.A.S.              | FR |
| PENTASA® 500 mg, comprimé                              | not available | 3400933278885     | FERRING S.A.S.              | FR |
| PENTASA 500 mg Retardtabletten                         | not available | 16944.00.01       | FERRING GMBH                | DE |
| PENTASA 1 g žvakutės                                   | not available | LT/1/96/1965/007  | FERRING GMBH                | LT |

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| PENTASA 500 mg<br>comprese a rilascio<br>modificato | not available | 027130071       | FERRING S.P.A.  | IT |
| PENTASA, 1 g, czopki                                | not available | R/6568          | FERRING GMBH  | PL |
| PENTASA® 500 mg,<br>comprimé                        | not available | 3400933278717   | FERRING S.A.S.  | FR |
| PENTASA® 500 mg,<br>comprimé                        | not available | 3400933278885   | FERRING S.A.S.  | FR |
| PENTASA 500 mg<br>Retardtabletten                   | not available | 16944.00.01     | FERRING GMBH  | DE |
| Pentasa 1 g végbélkúp                               | not available | OGYI-T- 4798/02 | FERRING MAGYARORSZÁG<br>GYÓGYSZERKERESKEDELMI<br>KFT. | HU |
| Pentasa 1 g rektálna<br>suspenszia                  | not available | 29/0319/00-S    | FERRING LÉCIVA A.S.                                   | SK |
| Pentasa 500 mg ilgstošās<br>darbības tabletes       | not available | 98-0118         | FERRING GMBH  | LV |
| PENTASA 1g compresse<br>a rilascio modificato       | not available | 027130107       | FERRING S.P.A.  | IT |
| Pentasa 1 g comprimés à<br>libération prolongée     | not available | 2016040070      | FERRING N.V.  | LU |
| PENTASA® 500 mg,<br>comprimé                        | not available | 3400933278717   | FERRING S.A.S.  | FR |

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|---|---------------|---------------|---|----|
| PENTASA® 500 mg, comprimé                         | not available | 3400933278885 | FERRING S.A.S.  | FR |
| PENTASA 500 mg Retardtabletten                    | not available | 16944.00.01   | FERRING GMBH  | DE |
| Pentasa 500 mg comprimés à libération prolongée   | not available | 2009050316    | FERRING N.V.  | LU |
| PENTASA 500 mg compresse a rilascio modificato    | not available | 027130071     | FERRING S.P.A.  | IT |
| Pentasa 500 mg Retardtabletten                    | not available | 2009050316    | FERRING N.V.  | LU |
| Pentasa 1 g Retardtabletten                       | not available | 2016040070    | FERRING N.V.  | LU |
| PENTASA, 4 g, granulato o przedłużonym uwalnianiu | not available | 23149         | FERRING GMBH  | PL |
| PENTASA, 1 g, granulato o przedłużonym uwalnianiu | not available | 8553          | FERRING GMBH  | PL |
| PENTASA, 2 g, granulato o przedłużonym uwalnianiu | not available | 20100         | FERRING GMBH  | PL |
| Pentasa 1000 mg/100 ml Suspensão retal            | not available | 2233286       | FERRING PORTUGUESA –<br>PRODUTOS<br>FARMACÊUTICOS,<br>SOCIEDADE UNIPESSOAL,<br>LDA. | PT |

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| Pentasa1000 mg/100 ml<br>Suspensão retal            | not available | 3968682              | FERRING PORTUGUESA –<br>PRODUTOS<br>FARMACÊUTICOS,<br>SOCIEDADE UNIPESSOAL,<br>LDA. | PT |
| Salcrozine 500 mg<br>gastro-resistant tablets.      | ES/H/0588/001 | PL 18945/0002 - 0001 | FAES FARMA, S.A.  | UK |
| Azzavix 500 mg<br>magensaftresistente<br>Tabletten  | ES/H/0588/001 | 139270               | FAES FARMA, S.A.  | AT |
| Salcrozine, 500 mg,<br>tabletki dojelitowe          | ES/H/0588/001 | 25650                | FAES FARMA, S.A.  | PL |
| Mecolvix 500 mg<br>comprimidos<br>gastroresistentes | ES/H/0588/001 | 84675                | FAES FARMA, S.A.  | ES |
| ASAVIXIN 2 G<br>SOSPENSIONE RETTALE                 | not available | 035356031            | MEDA PHARMA S.P.A.  | IT |
| Colitofalk 250 mg<br>suppositoires                  | not available | 1982/11051158        | DR. FALK PHARMA BENELUX<br>B.V.   | LU |
| PENTASA® 500 mg,<br>comprimé                        | not available | 3400933278717        | FERRING S.A.S.  | FR |
| PENTASA® 500 mg,<br>comprimé                        | not available | 3400933278885        | FERRING S.A.S.  | FR |
| PENTASA 500 mg<br>Retardtabletten                   | not available | 16944.00.01          | FERRING GMBH  | DE |

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| Pentasa 1 g prolonged-release tablets                             | not available | PA 1009/006/007   | FERRING IRELAND LTD.        | IE |
| PENTASA® 500 mg, comprimé   | not available | 3400933278717     | FERRING S.A.S.              | FR |
| PENTASA® 500 mg, comprimé   | not available | 3400933278885     | FERRING S.A.S.              | FR |
| PENTASA 500 mg Retardtabletten                                    | not available | 16944.00.01       | FERRING GMBH                | DE |
| PENTASA 4 g/100 ml sospensione rettale.                           | not available | 027130044         | FERRING S.P.A.              | IT |
| Asacol 400 mg, Γαστροανθεκτικά δισκία                             | not available | 30723/03-05-2012  | ANGELINI PHARMA HELLAS S.A. | GR |
| FIVASA 800 mg, comprimé enrobé gastrorésistant                    | not available | 34009 358 567 9 1 | TILLOTTS PHARMA GMBH        | FR |
| FIVASA 800 mg, comprimé enrobé gastrorésistant                    | not available | 34009 358 568 5 2 | TILLOTTS PHARMA GMBH        | FR |
| Pentasa Slow release tablets 1 g tablety s predĺženým uvoľňovaním | not available | 29/0532/10-S      | FERRING LÉCIVA A.S.         | SK |
| FIVASA 500 mg, suppositoire                                       | not available | 34009 356 683 1 8 | TILLOTTS PHARMA GMBH        | FR |
| FIVASA 500 mg, suppositoire                                       | not available | 34009 358 811 7 5 | TILLOTTS PHARMA GMBH        | FR |

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| FIVASA 500 mg, suppositoire                           | not available | 34009 358 810 0 7 | TILLOTTS PHARMA GMBH         | FR |
| PENTASA® 1 g/100 ml, suspension rectale               | not available | 3400932934744     | FERRING S.A.S.               | FR |
| Салофалк 4g/60 ml клизми                              | not available | 9600070           | DR FALK PHARMA GMBH          | BG |
| Pentasa Prolong 1g tablety s prodlouženým uvolňováním | not available | 29/011/11-C       | FERRING LÉCIVA A.S.          | CZ |
| Asacol 400 mg magensaftresistente Tabletten           | not available | 7135.00.00        | TILLOTTS PHARMA GMBH         | DE |
| Claversal® 500 mg Zäpfchen                            | not available | 5697.01.00        | RECORDATI PHARMA GMBH        | DE |
| Asacol 400 mg enterosolventní tablety                 | not available | 29/169/97-C       | TILLOTTS PHARMA GMBH         | CZ |
| Pentasa 1 g endaparmsdreifa.                          | not available | 880163 (IS)       | FERRING LÆGEMIDLER A/S       | IS |
| Colitofalk 2 g suspension rectale                     | not available | 1982/11051156     | DR. FALK PHARMA BENELUX B.V. | LU |
| Salofalk 500 mg čepíci                                | not available | HR-H-366666368    | WURTH D.O.O.                 | HR |
| Pentasa, rektalvæske, suspension, enkeltdosisbeholder | not available | 11718             | FERRING LÆGEMIDLER A/S       | DK |

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| PENTASA čípky   | not available | 29/009/95 - C | FERRING LÉCIVA A.S.             | CZ |
| PENTASA 1g compresse a rilascio modificato                    | not available | 027130107     | FERRING S.P.A.                  | IT |
| PENTASA® 500 mg, comprimé                                     | not available | 3400933278717 | FERRING S.A.S.                  | FR |
| PENTASA® 500 mg, comprimé                                     | not available | 3400933278885 | FERRING S.A.S.                  | FR |
| PENTASA 500 mg Retardtabletten                                | not available | 16944.00.01   | FERRING GMBH                    | DE |
| Pentasa 1 g supozitoriji                                      | not available | 97-0616       | FERRING GMBH                    | LV |
| PENTASA 500 mg compresse a rilascio modificato                | not available | 027130071     | FERRING S.P.A.                  | IT |
| ASACOL 800 mg enterotabletter                                 | not available | 16882         | TILLOTTS PHARMA AB              | FI |
| Asacol 800 mg enterotabletit                                  | not available | 16882         | TILLOTTS PHARMA AB              | FI |
| Pentasa Sachet 4 g granule s prodlouženým uvolňováním v sáčku | not available | 29/109/16-C   | FERRING LÉCIVA A.S.             | CZ |
| ASACOL 4 g in 100 mL enema                                    | not available | 19627         | TILLOTTS PHARMA GMBH            | CY |
| Pentasa 1 g - Zäpfchen  | not available | 1-20055       | FERRING ARZNEIMITTEL GES.M.B.H. | AT |

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| Asacol 400 mg<br>magensaftresistente<br>Tabletten      | not available | 137394    | HAEMO PHARMA GMBH     | AT |
| CLAVERSAL 500 mg<br>comprese rivestite                 | not available | 027308016 | TEOFARMA S.R.L.       | IT |
| PENTACOL 1,5 g<br>granulato per<br>sospensione rettale | not available | 026925038 | SOFAR S.P.A.          | IT |
| PENTACOL 4 g/100 ml<br>Sospensione rettale             | not available | 026925141 | SOFAR S.P.A.          | IT |
| Pentasa Sachet 4 g<br>depotgranulat                    | not available | 14-10423  | FERRING LEGEMIDLER AS | NO |
| PENTASA 500 mg<br>depottabletter                       | not available | 7762      | FERRING LEGEMIDLER AS | NO |
| Pentasa 1 g<br>depottabletter                          | not available | 09-6965   | FERRING LEGEMIDLER AS | NO |
| PENTASA Sachet 1 g<br>depotgranulat                    | not available | 98-5186   | FERRING LEGEMIDLER AS | NO |
| PENTASA Sachet 2 g<br>depotgranulat                    | not available | 04-2948   | FERRING LEGEMIDLER AS | NO |
| Claversal 500 mg<br>comprimidos<br>gastroresistentes   | not available | 58.101    | FAES FARMA, S.A.      | ES |
| Pentasa 500 mg<br>depottabletter                       | not available | 12307     | FERRING LÄKEMEDEL AB  | SE |



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| Pentasa 1 g depottabletter                                 | not available | 42950          | FERRING LÄKEMEDEL AB  | SE |
| Pentasa 500 mg tablete s podaljšanim sproščanjem           | not available | H/12/01972/001 | FERRING GMBH          | SI |
| Claversal® 500 mg Tabletten, magensaftresistente Tabletten | not available | 5697.01.01     | RECORDATI PHARMA GMBH | DE |
| PENTASA, 1 g/100 ml, zawiesina doodbytnicza                | not available | 8188           | FERRING GMBH          | PL |
| PENTASA® 500 mg, comprimé                                  | not available | 3400933278717  | FERRING S.A.S.        | FR |
| PENTASA® 500 mg, comprimé                                  | not available | 3400933278885  | FERRING S.A.S.        | FR |
| PENTASA 500 mg Retardtabletten                             | not available | 16944.00.01    | FERRING GMBH          | DE |
| PENTASA 1 g supposte                                       | not available | 027130069      | FERRING S.P.A.        | IT |
| Pentasa Sachet 2 g granulát s predĺženým uvoľňovaním       | not available | 29/0155/07-S   | FERRING LÉCIVA A.S.   | SK |
| Pentasa Sachet 4 g granulát s predĺženým uvoľňovaním       | not available | 29/0187/17-S   | FERRING LÉCIVA A.S.   | SK |
| Claversal 500 mg supositorios                              | not available | 60.607         | FAES FARMA, S.A.      | ES |

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| Colitofalk 4 g suspension rectale                          | not available | 1982/11051157 | DR. FALK PHARMA BENELUX B.V. | LU |
| PENTASA 1g/100 ml peräruiskesuspensio                      | not available | 9527          | FERRING LÄÄKKEET OY          | FI |
| Pentacol 400 mg, gastro-resistant modified-release tablets | not available | MA 133/00201  | SOFAR S.P.A.                 | MT |
| PENTACOL 500mg suppositories                               | not available | MA133/00202   | SOFAR S.P.A.                 | MT |
| PENTACOL 500 mg gel rettale                                | not available | 026925065     | SOFAR S.P.A.                 | IT |
| PENTACOL 500 mg gel rettale                                | not available | 026925180     | SOFAR S.P.A.                 | IT |
| PENTACOL 500mg supposte                                    | not available | 026925154     | SOFAR S.P.A.                 | IT |
| PENTASA® 500 mg, comprimé                                  | not available | 3400933278717 | FERRING S.A.S.               | FR |
| PENTASA® 500 mg, comprimé                                  | not available | 3400933278885 | FERRING S.A.S.               | FR |
| PENTASA 500 mg Retardtabletten                             | not available | 16944.00.01   | FERRING GMBH                 | DE |
| Asacol 800 mg comprimidos gastrorresistentes               | not available | 78448         | TILLOTTS PHARMA SPAIN S.A.   | ES |

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| Salofalk 500 mg suppositories                                    | not available  | MA 026/00103    | DR FALK PHARMA GMBH  | MT |
| Salofalk 500 mg suppositories                                    | not available  | 13057           | DR FALK PHARMA GMBH  | CY |
| Asacol, tabletter med modificeret udløsning                      | SE/H/1654/0001 | 59072           | TILLOTTS PHARMA AB   | DK |
| Asacolon 1600 mg modified-release tablets                        | SE/H/1654/001  | PA 2018/004/001 | TILLOTTS PHARMA GMBH | IE |
| Asacol 1600 mg tablety s řízeným uvolňováním                     | SE/H/1654/001  | 29/034/17-C     | TILLOTTS PHARMA GMBH | CZ |
| Yaldigo 1600 mg Tabletten mit veränderter Wirkstofffreisetzung   | SE/H/1654/001  | 138193          | TILLOTTS PHARMA GMBH | AT |
| Yaldigo 1600 mg modificētās darbības tabletes                    | SE/H/1654/001  | 18-0046         | TILLOTTS PHARMA AB   | LV |
| Yaldigo, 1600 mg toimeainet modifitseeritult vabastavad tabletid | SE/H/1654/001  | 961518          | TILLOTTS PHARMA AB   | EE |
| Asacol 1600 mg töflur með breyttan losunarhraða.                 | SE/H/1654/001  | IS/1/18/021/01  | TILLOTTS PHARMA AB   | IS |

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| Yaldigo 1600 mg,<br>tabletten met<br>gereguleerde afgifte                          | SE/H/1654/001 | RVG 120637       | TILLOTTS PHARMA GMBH | NL |
| Asacol 1600 mg<br>modifikuoto<br>atpalaidavimo tabletės                            | SE/H/1654/001 | LT/1/18/4201/001 | TILLOTTS PHARMA AB   | LT |
| Asacol 1600 mg<br>modifikuoto<br>atpalaidavimo tabletės                            | SE/H/1654/001 | LT/1/18/4201/002 | TILLOTTS PHARMA AB   | LT |
| Asacol 1600 mg<br>modifikuoto<br>atpalaidavimo tabletės                            | SE/H/1654/001 | LT/1/18/4201/003 | TILLOTTS PHARMA AB   | LT |
| Asacol 1600 mg tabletter<br>med modifisert frisetting                              | SE/H/1654/001 | 17-11557         | TILLOTTS PHARMA AB   | NO |
| Mesalazine Tillotts 1600<br>mg, tablet met<br>gereguleerde afgifte                 | SE/H/1654/001 | BE 232822        | TILLOTTS PHARMA GMBH | BE |
| Mesalazine Tillotts 1600<br>mg, comprimés à<br>libération modifiée                 | SE/H/1654/001 | BE 232822        | TILLOTTS PHARMA GMBH | BE |
| Mesalazine Tillotts 1600<br>mg Tablette mit<br>veränderter<br>Wirkstofffreisetzung | SE/H/1654/001 | BE 232822        | TILLOTTS PHARMA GMBH | BE |

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| Asacol 1600 mg säädellysti vapauttavat tabletit               | SE/H/1654/001 | 34959         | TILLOTTS PHARMA AB       | FI |
| Asacol 1600 mg tabletter med modifierad frisättning           | SE/H/1654/001 | 55999         | TILLOTTS PHARMA AB       | SE |
| Octasa 1600 mg modified-release tablets                       | SE/H/1654/001 | PL 36633/0009 | TILLOTTS PHARMA UK, LTD. | UK |
| Asacol 1600 mg Tabletten mit veränderter Wirkstofffreisetzung | SE/H/1654/001 | 2202543.00.00 | TILLOTTS PHARMA GMBH     | DE |
| Mesalazine Tillotts 1600 mg, comprimés à libération modifiée  | SE/H/1654/001 | 0872034       | TILLOTTS PHARMA GMBH     | LU |
| Mesalazine Tillotts 1600 mg, comprimés à libération modifiée  | SE/H/1654/001 | 0872048       | TILLOTTS PHARMA GMBH     | LU |
| Mesalazine Tillotts 1600 mg, comprimés à libération modifiée  | SE/H/1654/001 | 0872051       | TILLOTTS PHARMA GMBH     | LU |
| Mesalazina ESPL 1600 mg compresse a rilascio modificato       | SE/H/1654/001 | 046851010     | TILLOTTS PHARMA GMBH     | IT |

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| Mesalazina ESPL 1600 mg compresse a rilascio modificato | SE/H/1654/001 | 046851022             | TILLOTTS PHARMA GMBH | IT |
| Mesalazina ESPL 1600 mg compresse a rilascio modificato | SE/H/1654/001 | 046851034             | TILLOTTS PHARMA GMBH | IT |
| Mesalazine ESPL 1600 mg modified-release tablets        | SE/H/1654/001 | 1152/00301            | TILLOTTS PHARMA GMBH | MT |
| Pentasa 1 g tablete s produljenim oslobađanjem          | not available | UP/I-530-09/11-01/364 | FERRING GMBH         | HR |
| Pentasa 500 mg tablete s produljenim oslobađanjem       | not available | HR-H-120226953        | FERRING GMBH         | HR |
| PENTASA1 g comprimidos de liberación prolongada         | not available | 77022                 | FERRING S.A.U.       | ES |
| Salofalk 4 g rektalna suspenzija                        | not available | H/00/02032/009        | DR FALK PHARMA GMBH  | SI |
| Pentasa Sachet 4 g granulés à libération prolongée      | not available | BE506604              | FERRING N.V.         | BE |
| Pentasa Sachet 4 g granulaat met verlengde afgifte      | not available | BE506604              | FERRING N.V.         | BE |

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| Pentasa Sachet 4 g<br>Retardgranulat                       | not available | BE506604      | FERRING N.V.  | BE |
| Pentasa 1000 mg<br>Comprimidos de<br>libertação prolongada | not available | 5323845       | FERRING PORTUGUESA –<br>PRODUTOS<br>FARMACÊUTICOS,<br>SOCIEDADE UNIPessoal,<br>LDA. | PT |
| Pentasa 500 mg<br>Comprimido de<br>Libertação Prolongada   | not available | 2178887       | FERRING PORTUGUESA –<br>PRODUTOS<br>FARMACÊUTICOS,<br>SOCIEDADE UNIPessoal,<br>LDA. | PT |
| Pentasa 500 mg<br>Comprimido de<br>Libertação Prolongada   | not available | 2178986       | FERRING PORTUGUESA –<br>PRODUTOS<br>FARMACÊUTICOS,<br>SOCIEDADE UNIPessoal,<br>LDA. | PT |
| Colitofalk 500 mg<br>suppositoires                         | not available | 1982/11051159 | DR. FALK PHARMA BENELUX<br>B.V.   | LU |
| Pentasa 1g/100 ml,<br>suspensie voor rectaal<br>gebruik    | not available | RVG 11782     | FERRING B.V.  | NL |
| Zintasa 400mg Enteric-<br>Coated Tablets                   | not available | PL 20117/0335 | MORNINGSIDE HEALTHCARE<br>LTD   | UK |
| Mesalazine 400mg<br>Enteric-Coated Tablets                 | not available | PL 20117/0335 | MORNINGSIDE HEALTHCARE<br>LTD   | UK |

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| Panzin 400mg Enteric-Coated Tablets                  | not available | PL 20117/0335 | MORNINGSIDE HEALTHCARE LTD  | UK |
| Pentasa 1000 mg Supositórios                         | not available | 2177384       | FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPessoal, LDA. | PT |
| CLAVERSAL 500 mg suppositoires                       | not available | 2000065845    | TRAMEDICO N.V.  | LU |
| CLAVERSAL Foam 1g/dose, mousse rectale               | not available | 1995070317    | TRAMEDICO N.V.  | LU |
| CLAVERSAL 500 mg maagsapresistente tabletten         | not available | BE213534      | TRUVION HEALTHCARE N.V  | BE |
| CLAVERSAL 500 mg comprimés gastro-résistants         | not available | BE213534      | TRUVION HEALTHCARE N.V  | BE |
| CLAVERSAL 500 mg zetpillen                           | not available | BE144882      | TRUVION HEALTHCARE N.V  | BE |
| CLAVERSAL 500 mg Suppositoires                       | not available | BE144882      | TRUVION HEALTHCARE N.V  | BE |
| CLAVERSAL Foam 1g/dosis, schuim voor rectaal gebruik | not available | BE169592      | TRUVION HEALTHCARE N.V  | BE |



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|---|---------------|-----------------|---|----|
| CLAVERSAL Foam<br>1g/dose, mousse rectale           | not available | BE169592        | TRUVION HEALTHCARE N.V                                | BE |
| CLAVERSAL 500 mg<br>comprimés gastro-<br>résistants | not available | 2001040038      | TRAMEDICO N.V.  | LU |
| PENTASA® 500 mg,<br>comprimé                        | not available | 3400933278717   | FERRING S.A.S.  | FR |
| PENTASA® 500 mg,<br>comprimé                        | not available | 3400933278885   | FERRING S.A.S.  | FR |
| PENTASA 500 mg<br>Retardtabletten                   | not available | 16944.00.01     | FERRING GMBH  | DE |
| Pentasa 500 mg retard<br>tabletta                   | not available | OGYI-T- 4798/01 | FERRING MAGYARORSZÁG<br>GYÓGYSZERKERESKEDELMI<br>KFT. | HU |
| Pentasa 1 g retard<br>tabletta                      | not available | OGYI-T- 4798/05 | FERRING MAGYARORSZÁG<br>GYÓGYSZERKERESKEDELMI<br>KFT. | HU |
| Pentasa 1 g čapíky                                  | not available | 29/0425/95-S    | FERRING LÉCIVA A.S.                                   | SK |
| PENTASA 1 g<br>rektalvæske, suspensjon              | not available | 7402            | FERRING LEGEMIDLER AS                                 | NO |
| PENTASA 1 g stikkpiller                             | not available | 03-2326         | FERRING LEGEMIDLER AS                                 | NO |
| PENTASA® 500 mg,<br>comprimé                        | not available | 3400933278717   | FERRING S.A.S.  | FR |

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| PENTASA® 500 mg, comprimé                    | not available | 3400933278885   | FERRING S.A.S.                                  | FR |
| PENTASA 1000 mg Retardtabletten              | not available | 78793.00.00     | FERRING GMBH                                    | DE |
| PENTASA® Mesalazine Enema                    | not available | PL 3194/0027    | FERRING PHARMACEUTICALS LTD.                    | UK |
| Claversal 1 g comprimidos gastrorresistentes | not available | 83162           | FAES FARMA, S.A.                                | ES |
| Claversal 1g espuma Rectal                   | not available | 61.335          | FAES FARMA, S.A.                                | ES |
| Pentasa 4 g retard granulátum                | not available | OGYI-T- 4798/06 | FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDELMI KFT. | HU |
| PENTASA® 500 mg, comprimé                    | not available | 3400933278717   | FERRING S.A.S.                                  | FR |
| PENTASA® 500 mg, comprimé                    | not available | 3400933278885   | FERRING S.A.S.                                  | FR |
| PENTASA 500 mg Retardtabletten               | not available | 16944.00.01     | FERRING GMBH                                    | DE |
| Pentasa 2 g retard granulátum                | not available | OGYI-T- 4798/04 | FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDELMI KFT. | HU |
| Pentasa 1 g suppositoires                    | not available | BE164972        | FERRING N.V.                                    | BE |

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|---|---------------|---------------|------------------------------|----|
| Pentasa 1 g zetpillen                                 | not available | BE164972      | FERRING N.V.                 | BE |
| Pentasa 1 g Zäpfchen                                  | not available | BE164972      | FERRING N.V.                 | BE |
| Pentasa Sachet 1 g granulaat met verlengde afgifte    | not available | BE209772      | FERRING N.V.                 | BE |
| Pentasa Sachet 2 g granulaat met verlengde afgifte    | not available | BE343734      | FERRING N.V.                 | BE |
| Pentasa Sachet 1 g granulés à libération prolongée    | not available | BE209772      | FERRING N.V.                 | BE |
| Pentasa Sachet 2 g granulés à libération prolongée    | not available | BE343734      | FERRING N.V.                 | BE |
| Pentasa Sachet 1 g Retardgranulat                     | not available | BE209772      | FERRING N.V.                 | BE |
| Pentasa Sachet 2 g Retardgranulat                     | not available | BE343734      | FERRING N.V.                 | BE |
| Colitofalk 250 mg comprimés gastro-résistants         | not available | 1982/11051168 | DR. FALK PHARMA BENELUX B.V. | LU |
| Салофалк 500 mg стомашно-устойчиви таблетки мезалазин | not available | 9600067       | DR FALK PHARMA GMBH          | BG |

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|--|---------------|-----------------------|------------------------|----|
| PENTASA 500 mg comprimidos de liberación prolongada    | not available | 60.152                | FERRING S.A.U.         | ES |
| PENTASA® 1 g depottablett                              | not available | 27787                 | FERRING LÄÄKKEET OY    | FI |
| PENTASA 1 g depottabletti                              | not available | 27787                 | FERRING LÄÄKKEET OY    | FI |
| Pentasa vrećice 2 g granule s produjjenim oslobađanjem | not available | UP/I-530-09/12-01/601 | FERRING GMBH           | HR |
| Пентаза 500 mg таблетки с удължено освобождаване       | not available | 9900187               | FERRING GMBH           | BG |
| Pentasa, depottabletter                                | not available | 13655                 | FERRING LÆGEMIDLER A/S | DK |
| Pentasa, depottabletter                                | not available | 45626                 | FERRING LÆGEMIDLER A/S | DK |
| PENTASA čípky  | not available | 29/009/95 - C         | FERRING LÉCIVA A.S.    | CZ |
| Asacol 800 mg magensaftresistente Tabletten            | not available | 89227.00.00           | TILLOTTS PHARMA GMBH   | DE |
| Asacolon 800mg Gastro-resistant Tablets                | not available | PA2018/001/002        | TILLOTTS PHARMA GMBH   | IE |
| ASAVIXIN 4 G SOSPENSIONE RETTALE                       | not available | 035356043             | MEDA PHARMA S.P.A.     | IT |