



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

7 July 2016  
EMA/270645/2015  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: indapamide

Procedure no.: PSUSA/00001731/201511



| 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 |
|--------------------------------------------------------|--------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| Diuremid SR 1,5 mg, comprimate cu eliberare prelungita | not available                  | 1408/2009/01                  | GLENMARK PHARMACEUTICALS S.R.L     | RO                                       |
| INDAPAMIDE BIOGARAN® 2,5 mg, comprimé pelliculé        | not available                  | 3400932980468                 | BIOGARAN                           | FR                                       |
| Indapamid-CT 2,5 mg Hartkapseln                        | not available                  | 26345.00.00                   | ABZ-PHARMA GMBH                    | DE                                       |
| Indapamid-CT 2,5 mg Hartkapseln                        | not available                  | 26345.00.00                   | ABZ-PHARMA GMBH                    | DE                                       |
| Indapamid-CT 2,5 mg Hartkapseln                        | not available                  | 26345.00.00                   | ABZ-PHARMA GMBH                    | DE                                       |
| Indapamid-CT 2,5 mg Hartkapseln                        | not available                  | 26345.00.00                   | ABZ-PHARMA GMBH                    | DE                                       |
| Indapamide 2.5 mg tablets.                             | not available                  | PL 30464/0030                 | ATHLONE PHARMACEUTICALS LIMITED    | UK                                       |
| Ipamix                                                 | not available                  | 024150029                     | VISUFARMA SPA                      | IT                                       |

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| TERTENSIF SR 1,5 mg filmom obložene tablete s produljenim oslobađanjem | not available                  | UP/I-530-09/13-02/14          | SERVIER PHARMA D.O.O - CROATIA                       | HR                                       |
| NATRILIX SR 1.5 mg, prolonged-release film-coated tablets              | FR/H/0100/001                  | MA 066/00901                  | LES LABORATOIRES SERVIER (SURESNES)                  | MT                                       |
| Apadex 1,5 mg retard filmtabletta                                      | FR/H/0135/001/MR               | OGYI-T-10268/01               | EGIS PHARMACEUTICALS PLC                             | HU                                       |
| INDAPAMIDE BIOGARAN® 1,5 mg, comprimé pelliculé à libération prolongée | FR/H/0135/001                  | NL 19836                      | BIOGARAN                                             | FR                                       |
| Tandix LP 1,5 mg comprimidos de libertação prolongada                  | FR/H/135/01                    | 3675188                       | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                       |
| Tandix LP 1,5 mg comprimidos de libertação prolongada                  | FR/H/135/01                    | 4017281                       | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                       |
| Tandix LP 1,5 mg comprimidos de libertação prolongada                  | FR/H/135/01                    | 4017380                       | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                       |

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| Tandix LP 1,5 mg comprimidos de libertação prolongada | FR/H/135/01                           | 2871580                              | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                              |
| Tandix LP 1,5 mg comprimidos de libertação prolongada | FR/H/135/01                           | 4017489                              | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                              |
| Tandix LP 1,5 mg comprimidos de libertação prolongada | FR/H/135/01                           | 4484986                              | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                              |
| Tandix LP 1,5 mg comprimidos de libertação prolongada | FR/H/135/01                           | 3675287                              | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                              |
| Tandix LP 1,5 mg comprimidos de libertação prolongada | FR/H/135/01                           | 4017588                              | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                              |
| Tandix 2,5 mg comprimidos revestidos                  | not available                         | 9494724                              | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                              |
| Tandix 2,5 mg comprimidos revestidos                  | not available                         | 4704599                              | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                              |
| Tandix 2,5 mg comprimidos revestidos                  | not available                         | 9494716                              | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                              |

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| Tandix 2,5 mg comprimidos revestidos                         | not available                         | 4704698                              | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                              |
| Tandix LP 1,5 mg comprimidos de libertação prolongada        | FR/H/135/01                           | 4017182                              | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                              |
| Tandix 2,5mg comprimidos revestidos                          | not available                         | 4704490                              | LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A. | PT                                              |
| FLUDEX 2,5 mg comprimés enrobés                              | not available                         | BE091725                             | SERVIER R&D BENELUX N.V./S.A.                        | BE                                              |
| FLUDEX 2,5 mg omhulde tabletten                              | not available                         | BE091725                             | SERVIER R&D BENELUX N.V./S.A.                        | BE                                              |
| FLUDEX 2,5 mg überzogene Tabletten                           | not available                         | BE091725                             | SERVIER R&D BENELUX N.V./S.A.                        | BE                                              |
| Fludex SR 1,5 mg filmomhulde tabletten met verlengde afgifte | FR/H/100/01                           | RVG 19206                            | LES LABORATOIRES SERVIER (SURESNES)                  | NL                                              |
| ТЕРПЕНСИФ SR 1,5 mg таблетки с удължено освобождаване        | not available                         | 20000134                             | LES LABORATOIRES SERVIER (SURESNES)                  | BG                                              |

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| Fludex retard 1,5 mg -<br>Filmtabletten                                                    | FR/H/0100/001                         | 1-21433                              | LES LABORATOIRES SERVIER<br>(SURESNES)    | AT                                              |
| TERTENSIF SR 1,5 mg<br>filmsko obložene tablete s<br>podaljšanim sproščanjem               | FR/H/0100/001                         | 5363-I-1739/10                       | SERVIER PHARMA D.O.O                      | SI                                              |
| TERTENSIF SR                                                                               | FR/H/100/01                           | 58/621/97-C                          | LES LABORATOIRES SERVIER<br>(SURESNES)    | CZ                                              |
| TERTENSIF SR filmom<br>obalené tablety s<br>predĺženým uvoľňovaním                         | FR/H/0100/001                         | 58/0166/05-S                         | LES LABORATOIRES SERVIER<br>(SURESNES)    | SK                                              |
| TERTENSIF SR 1,5 mg<br>filmsko obložene tablete s<br>podaljšanim sproščanjem               | FR/H/0100/001                         | 5363-I-1738/10                       | SERVIER PHARMA D.O.O                      | SI                                              |
| FLUDEX 1.5MG<br>comprimés à libération<br>prolongée                                        | FR/H/100/01                           | BE178306                             | SERVIER R&D BENELUX<br>N.V./S.A.          | BE                                              |
| Pretanix 1,5 mg retard<br>filmtabletta                                                     | FR/H/0100/001                         | OGYI-T-6788/01                       | LES LABORATOIRES SERVIER<br>(SURESNES)    | HU                                              |
| Indapamide 1,5 mg SR<br>Servier 1,5 mg, tabletki<br>powlekane o<br>przedłużonym uwalnianiu | FR/H/0100/001                         | 11501                                | LES LABORATOIRES SERVIER<br>(SURESNES)    | PL                                              |

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| Tertensif SR 1,5 mg, tabletki powlekane o przedłużonym uwalnianiu | not available                         | R/7382                               | LES LABORATOIRES SERVIER (SURESNES)       | PL                                              |
| FLUDEX 1,5 mg Retard-Filmtabletten                                | FR/H/100/01                           | BE178306                             | SERVIER R&D BENELUX N.V./S.A.             | BE                                              |
| FLUDEX 1,5 mg, filmomhulde tablet met verlengde afgifte           | FR/H/100/01                           | BE178306                             | SERVIER R&D BENELUX N.V./S.A.             | BE                                              |
| Tertensif SR 1,5 mg comprimate cu eliberare prelungită            | not available                         | 1901/2009/05                         | LES LABORATOIRES SERVIER (SURESNES)       | RO                                              |
| Tertensif SR 1,5 mg comprimate cu eliberare prelungită            | not available                         | 1901/2009/03                         | LES LABORATOIRES SERVIER (SURESNES)       | RO                                              |
| Tertensif SR 1,5 mg comprimate cu eliberare prelungită            | not available                         | 1901/2009/01                         | LES LABORATOIRES SERVIER (SURESNES)       | RO                                              |
| Tertensif SR 1,5 mg comprimate cu eliberare prelungită            | not available                         | 1901/2009/04                         | LES LABORATOIRES SERVIER (SURESNES)       | RO                                              |
| Tertensif SR 1,5 mg comprimate cu eliberare prelungită            | not available                         | 1901/2009/02                         | LES LABORATOIRES SERVIER (SURESNES)       | RO                                              |

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| FLUDEX 1,5 mg, επικαλυμμένα με λεπτό υμένιο δισκία παρατεταμένης αποδέσμευσης | FR/H/0100/001                  | 19694                         | LES LABORATOIRES SERVIER (SURESNES)                  | CY                                       |
| FLUDEX 2.5MG                                                                  | not available                  | 8353                          | LES LABORATOIRES SERVIER (SURESNES)                  | CY                                       |
| FLUDEX 1,5 mg, επικαλυμμένα με λεπτό υμένιο δισκία παρατεταμένης αποδέσμευσης | FR/H/100/01                    | 77156/27-11-2007              | SERVIER HELLAS                                       | GR                                       |
| FLUDEX 1,5 mg, comprimé pelliculé à libération prolongée                      | FR/H/0100/001                  | 1999126408                    | LES LABORATOIRES SERVIER (SURESNES)                  | LU                                       |
| FLUDEX 2,5 mg, comprimé pelliculé                                             | not available                  | 2007049254                    | LES LABORATOIRES SERVIER (SURESNES)                  | LU                                       |
| FLUDEX LP 1,5 mg comprimidos de libertação prolongada                         | FR/H/0100/001                  | 3830486                       | SERVIER PORTUGAL, ESPECIALIDADES FARMACÊUTICAS, LDA. | PT                                       |
| FLUDEX LP 1,5 mg comprimidos de libertação prolongada                         | FR/H/0100/001                  | 3675386                       | SERVIER PORTUGAL, ESPECIALIDADES FARMACÊUTICAS, LDA. | PT                                       |

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| FLUDEX LP 1,5 mg comprimidos de libertação prolongada | FR/H/0100/001                         | 8438341                              | SERVIER PORTUGAL, ESPECIALIDADES FARMACÊUTICAS, LDA. | PT                                              |
| Fludex 2,5 mg comprimidos revestidos                  | not available                         | 4704789                              | SERVIER PORTUGAL, ESPECIALIDADES FARMACÊUTICAS, LDA. | PT                                              |
| FLUDEX LP 1,5 mg comprimidos de libertação prolongada | FR/H/0100/001                         | 4485280                              | SERVIER PORTUGAL, ESPECIALIDADES FARMACÊUTICAS, LDA. | PT                                              |
| FLUDEX LP 1,5 mg comprimidos de libertação prolongada | FR/H/0100/001                         | 3830189                              | SERVIER PORTUGAL, ESPECIALIDADES FARMACÊUTICAS, LDA. | PT                                              |
| FLUDEX LP 1,5 mg comprimidos de libertação prolongada | FR/H/0100/001                         | 3830080                              | SERVIER PORTUGAL, ESPECIALIDADES FARMACÊUTICAS, LDA. | PT                                              |
| FLUDEX LP 1,5 mg comprimidos de libertação prolongada | FR/H/0100/001                         | 3675089                              | SERVIER PORTUGAL, ESPECIALIDADES FARMACÊUTICAS, LDA. | PT                                              |
| Fludex 2,5 mg comprimidos revestidos                  | not available                         | 8438325                              | SERVIER PORTUGAL, ESPECIALIDADES FARMACÊUTICAS, LDA. | PT                                              |
| FLUDEX LP 1,5 mg comprimidos de libertação prolongada | FR/H/0100/001                         | 3830387                              | SERVIER PORTUGAL, ESPECIALIDADES FARMACÊUTICAS, LDA. | PT                                              |

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| TERTENSIF 2,5 mg, comprimidos recubiertos con película                                  | not available                       | 53.338                               | LESTRAL S.A.                                         | ES                                              |
| TERTENSIF RETARD 1,5 mg, comprimidos recubiertos con película de liberación prolongada. | FR/H/100/01                         | 61.252                               | LES LABORATOIRES SERVIER (SURESNES)                  | ES                                              |
| FLUDEX LP 1,5 mg comprimidos de libertação prolongada                                   | FR/H/0100/001                       | 3830288                              | SERVIER PORTUGAL, ESPECIALIDADES FARMACÊUTICAS, LDA. | PT                                              |
| Natrilix SR 1,5 mg                                                                      | FR/H/100/01                         | 35649.00.00                          | LES LABORATOIRES SERVIER (SURESNES)                  | DE                                              |
| tertensif 2,5 mg plêvele dengtos tabletês                                               | not available                       | LT/1/94/0939/001                     | LES LABORATOIRES SERVIER (SURESNES)                  | LT                                              |
| TERTENSIF SR 1,5 mg pailginto atpalaidavimo tabletês                                    | FR/H/0100/001                       | LT/1/05/0203/002                     | LES LABORATOIRES SERVIER (SURESNES)                  | LT                                              |
| TERTENSIF SR 1,5 mg pailginto atpalaidavimo tabletês                                    | FR/H/0100/001                       | LT/1/05/0203/005                     | LES LABORATOIRES SERVIER (SURESNES)                  | LT                                              |
| TERTENSIF SR 1,5 mg pailginto atpalaidavimo tabletês                                    | FR/H/0100/001                       | LT/1/05/0203/006                     | LES LABORATOIRES SERVIER (SURESNES)                  | LT                                              |

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| TERTENSIF SR 1,5 mg pailginto atpalaidavimo tabletės                | FR/H/0100/001                       | LT/1/05/0203/009                     | LES LABORATOIRES SERVIER (SURESNES)       | LT                                              |
| TERTENSIF SR 1,5 mg pailginto atpalaidavimo tabletės                | FR/H/0100/001                       | LT/1/05/0203/003                     | LES LABORATOIRES SERVIER (SURESNES)       | LT                                              |
| TERTENSIF SR 1,5 mg pailginto atpalaidavimo tabletės                | FR/H/0100/001                       | LT/1/05/0203/007                     | LES LABORATOIRES SERVIER (SURESNES)       | LT                                              |
| TERTENSIF SR 1,5 mg pailginto atpalaidavimo tabletės                | FR/H/0100/001                       | LT/1/05/0203/008                     | LES LABORATOIRES SERVIER (SURESNES)       | LT                                              |
| TERTENSIF SR 1,5 mg pailginto atpalaidavimo tabletės                | FR/H/0100/001                       | LT/1/05/0203/001                     | LES LABORATOIRES SERVIER (SURESNES)       | LT                                              |
| TERTENSIF SR 1,5 mg pailginto atpalaidavimo tabletės                | FR/H/0100/001                       | LT/1/05/0203/004                     | LES LABORATOIRES SERVIER (SURESNES)       | LT                                              |
| Natrilix® Retard, filmovertukne depottabletter                      | FR/H/0100/001                       | 17556                                | LES LABORATOIRES SERVIER (SURESNES)       | DK                                              |
| TERTENSIF SR, 1,5 mg toimeainet prolongeeritult vabastavad tabletid | FR/H/0100/001                       | 241298                               | LES LABORATOIRES SERVIER (SURESNES)       | EE                                              |

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| TERTENSIF, 2,5 mg<br>õhukese<br>polümeerikattega tabletid                             | not available                  | 159097                        | LES LABORATOIRES SERVIER<br>(SURESNES) | EE                                       |
| Natrilix retard 1,5 mg<br>depotabletti                                                | FR/H/100/01                    | 12124                         | LES LABORATOIRES SERVIER<br>(SURESNES) | FI                                       |
| Indapamide SR Servier,<br>1,5 mg toimeainet<br>prolongeeritult<br>vabastavad tabletid | FR/H/0135/001                  | 472205                        | LES LABORATOIRES SERVIER<br>(SURESNES) | EE                                       |
| Natrilix 2.5 mg Tablets                                                               | not available                  | PL 00093/0022                 | SERVIER LABORATORIES<br>LTD            | UK                                       |
| FLUDEX 1.5mg SR<br>Tablets                                                            | FR/H/0160/001                  | PL 05815/0016                 | LES LABORATOIRES SERVIER<br>(SURESNES) | UK                                       |
| Tertensif SR 1,5mg<br>ilgstošas darbības<br>apvalkotās tabletes                       | FR/H/100/01                    | 05-0157                       | LES LABORATOIRES SERVIER<br>(SURESNES) | LV                                       |
| Tertensif retard 1,5 mg<br>depotabletti                                               | FR/H/160/01                    | 15008                         | LES LABORATOIRES SERVIER<br>(SURESNES) | FI                                       |
| NATRILIX SR 1.5 mg<br>Tablets                                                         | FR/H/0100/001                  | PL 05815/0010                 | LES LABORATOIRES SERVIER<br>(SURESNES) | UK                                       |

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| Tertensif 2,5 mg tabletti                                | not available                         | 11070                                | LES LABORATOIRES SERVIER (SURESNES)       | FI                                              |
| NATRILIX SR 1.5MG, PROLONGED-RELEASE FILM-COATED TABLETS | FR/H/0100/001                         | PA 568/5/1                           | LES LABORATOIRES SERVIER (SURESNES)       | IE                                              |
| Natrilix Retard 1,5 mg forðatöflur                       | not available                         | 960137                               | LES LABORATOIRES SERVIER (SURESNES)       | IS                                              |
| Natrilix 2,5 mg tabletti                                 | not available                         | 9789                                 | LES LABORATOIRES SERVIER (SURESNES)       | FI                                              |
| NATRILIX LP 1,5 mg compresse a rilascio prolungato       | FR/H/0100/001                         | 024032068/M                          | LES LABORATOIRES SERVIER (SURESNES)       | IT                                              |
| NATRILIX LP 1,5 mg compresse a rilascio prolungato       | FR/H/0100/001                         | 024032031/M                          | LES LABORATOIRES SERVIER (SURESNES)       | IT                                              |
| NATRILIX 2,5 mg compresse rivestite con film             | not available                         | 024032017                            | LES LABORATOIRES SERVIER (SURESNES)       | IT                                              |
| Natrilix® 2,5 mg Filmtabletten                           | not available                         | 6399261.00.0 0                       | LES LABORATOIRES SERVIER (SURESNES)       | DE                                              |

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| Fludex 2,5 mg filmomhulde tabletten            | not available                         | RVG 06787                            | SERVIER NEDERLAND FARMA B.V.              | NL                                              |
| Indapamide 2.5mg Tablets                       | not available                         | PL 36722/0037                        | SPECIAL CONCEPT DEVELOPMENT (UK) LTD      | UK                                              |
| Extur                                          | not available                         | 24/02/1900                           | Laboratorios Normon S.A.                  | ES                                              |
| INDAMOL (Indapamide)                           | not available                         | 024619049                            | TEOFARMA S.R.L.                           | IT                                              |