



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

30 November 2017  
EMA/797779/2017  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: latanoprost (products with paediatric indication)

Procedure no.: PSUSA/00001834/201704



| 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 |
|--|------------------------------|-------------------------------|--|--|
| Akistan 50 mikrogramov/ml očná roztoková instilácia  | SE/H/1095/001                | 64/0080/13-S                  | PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH | SK                                       |
| Akistan 0,05 mg/ml oldatos szemcsepp                 | SE/H/1095/001                | OGYI-T-22248/01               | PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH | HU                                       |
| Akistan 50 micrograme/ml picături oftalmice, soluție | SE/H/1095/001                | 5453/2013/01                  | PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH | RO                                       |
| Akistan 50 mikrogram/ml ögondroppar, lösning         | SE/H/1095/001                | 45460                         | PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH | SE                                       |
| Akistan 50 Mikrogramm/ml Augentropfen                | SE/H/1095/001                | 1-31279                       | PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH | AT                                       |
| Akistan 50 Mikrogramm/ml Augentropfen                | SE/H/1095/001                | 84058.00.00                   | PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH | DE                                       |
| Akistan 50 mikrogramov/ml kapljice za oko, raztopina | SE/H/1095/001                | 5363-I-2366/12                | PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH | SI                                       |
| Akistan 50 mikrogramų/ml akių lašai (tirpalas)       | SE/H/1095/001                | LT/1/12/2952/001              | PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH | LT                                       |
| Akistan 50 mikrogramů/ml oční kapky, roztok          | SE/H/1095/001                | 64/387/12-C                   | PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH | CZ                                       |
| Akistan, 50 mikrogramów/ml, krople do oczu, roztwór  | SE/H/1095/001                | 20362                         | PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH | PL                                       |

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|--|-------------------------------------|--------------------------------------|---|---|
| Arulatan 50 microgramos/ml, colirio en solución      | UK/H/1986/001                       | 72964                                | DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH | ES  |
| Gisolom 50 µg/ml eye drops solution                  | not available                       | 22356                                | DELORBIS PHARMACEUTICALS LTD              | CY  |
| Jaskroptic 0,05 mg/ml Augentropfen, Lösung           | DE/H/4399/001                       | 93873.00.00                          | VITAL PHARMA GMBH                         | DE  |
| Jaskroptic, 0,05 mg/ml, krople do oczu, roztwór      | DE/H/4399/001                       | 23467                                | VITAL PHARMA GMBH                         | PL  |
| Lanotan 50 mikrogramm/ml oldatos szemcsepp           | UK/H/1986/001                       | OGYI-T-21504/01                      | DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH | HU  |
| Latacris 50 microgram/ml eye drops, solution         | IE/H/0216/001                       | PA 2122/001/001                      | NTC SRL                                   | IE  |
| Latacris 50 microgram/ml eye drops, solution         | IE/H/0216/001                       | PL 35730/0013                        | NTC SRL                                   | UK  |
| Latacris, 50 mikrogramów/ml, krople do oczu, roztwór | IE/H/0216/001                       | 18946                                | SUN-FARM SP. Z.O.O.                       | PL  |
| Latacris® 50 Mikrogramm/ml Augentropfen              | not available                       | 1-31792                              | DERMAPHARM GMBH                           | AT  |

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|---|------------------------------|-------------------------------|---------------------------------------|--|
| Latadin 0,005% w/v<br>οφθαλμικές σταγόνες<br>διάλυμα      | not available                | 92288/15/20-01-2016           | ANFARM HELLAS SA                      | GR                                       |
| Latadin PF 0,005% w/v<br>οφθαλμικές σταγόνες<br>διάλυμα   | not available                | 3659/20-01-2016               | ANFARM HELLAS SA                      | GR                                       |
| LATALUX 50<br>microgram/ml,<br>oogdruppels, oplossing     | NL/H/1654/001                | RVG 104319                    | PHARMASWISS ČESKÁ<br>REPUBLIKA S.R.O. | NL                                       |
| Latalux 50 mikrogrami/ml<br>acu pilieni, šķīdums          | NL/H/1654/001                | 10-0502                       | PHARMASWISS ČESKÁ<br>REPUBLIKA S.R.O. | LV                                       |
| LATALUX 50<br>mikrogramov/ml očná<br>roztoková instilácia | NL/H/1654/001                | 64/0474/10-S                  | PHARMASWISS ČESKÁ<br>REPUBLIKA S.R.O. | SK                                       |
| LATALUX 50<br>mikrogramų/ml akių lašai<br>(tirpalas)      | NL/H/1654/001                | LT/1/10/2163/001              | PHARMASWISS ČESKÁ<br>REPUBLIKA S.R.O. | LT                                       |
| LATALUX 50<br>mikrogramų/ml akių lašai<br>(tirpalas)      | NL/H/1654/001                | LT/1/10/2163/002              | PHARMASWISS ČESKÁ<br>REPUBLIKA S.R.O. | LT                                       |
| LATALUX 50<br>mikrogramų/ml akių lašai<br>(tirpalas)      | NL/H/1654/001                | LT/1/10/2163/003              | PHARMASWISS ČESKÁ<br>REPUBLIKA S.R.O. | LT                                       |
| LATALUX 50<br>mikrogramů/ml oční<br>kapky, roztok         | NL/H/1654/001                | 64/584/10-C                   | PHARMASWISS ČESKÁ<br>REPUBLIKA S.R.O. | CZ                                       |

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| Latalux, 50 mikrogramów/ml, krople do oczu, roztwór | NL/H/1654/001                | 17247                         | PHARMASWISS ČESKÁ REPUBLIKA S.R.O. | PL                                       |
| Latanelb 50 Mikrogramm/ml Augentropfen              | not available                | 85823.00.00                   | AXUNIO PHARMA GMBH                 | DE                                       |
| LATANISTON 0,005% w/v Οφθαλμικές σταγόνες, διάλυμα  | not available                | 3196                          | NOVENDIA PHARMACEUTICALS LTD       | GR                                       |
| Latanomed® 50 Mikrogramm/ml Augentropfen            | IE/H/0216/001                | 80004.00.00                   | MIBE GMBH ARZNEIMITTEL             | DE                                       |
| Latanoprost "Mylan", øjendråber, opløsning          | SE/H/1283/001                | 52020                         | MYLAN AB                           | DK                                       |
| Latanoprost "Sandoz"                                | DE/H/2076/001                | 44410                         | SANDOZ A/S                         | DK                                       |
| Latanoprost "Stada", øjendråber, opløsning          | NL/H/1809/001                | 45622                         | STADA ARZNEIMITTEL AG              | DK                                       |
| Latanoprost 0.005% w/v eye drops solution           | NO/H/0139/001                | PL 00289/1668                 | TEVA UK LIMITED                    | UK                                       |
| Latanoprost 0.005% w/v eye drops solution           | UK/H/2707/001                | PL 17918/0014                 | TUBILUX PHARMA S.P.A.              | UK                                       |

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|---|-------------------------------------|--------------------------------------|---|---|
| Latanoprost 0.005% w/v eye drops, Solution                    | DE/H/2076/001                       | PL 04416/1051                        | SANDOZ LTD                                | UK  |
| Latanoprost- 1 A Pharma 50 Mikrogramm/ml Augentropfen, Lösung | DE/H/2076/001                       | 75073.00.00                          | 1 A PHARMA GMBH                           | DE  |
| Latanoprost 50 micrograms / ml Eye Drops, Solution.           | UK/H/4549/001                       | PL 35638 /0003                       | FDC PHARMA                                | UK  |
| Latanoprost 50 micrograms/ml eye drops solution               | UK/H/5209/001                       | PL 18157/0254                        | BEACON PHARMACEUTICALS LIMITED            | UK  |
| Latanoprost 50 micrograms/ml eye drops, solution              | SE/H/1283/001                       | PA0405/068/001                       | GENERICS [UK] LIMITED                     | IE  |
| Latanoprost 50 micrograms/ml eye drops, solution              | UK/H/5496/001                       | PL 24598/0045                        | NORIDEM ENTERPRISES LTD                   | UK  |
| Latanoprost Abamed 50 microgramos/ml colirio en solución.     | ES/H/0328/01                        | 71.100                               | ABAMED PHARMA, S.L.                       | ES  |
| Latanoprost AbZ 50 Mikrogramm/ml Augentropfen                 | not available                       | 86005.00.00                          | ABZ-PHARMA GMBH                           | DE  |
| Latanoprost AL 50 Mikrogramm/ml Augentropfen                  | NL/H/1810/001                       | 79742.00.00                          | ALIUD PHARMA GMBH                         | DE  |

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|---|-------------------------------------|--------------------------------------|---|---|
| LATANOPROST ARROW 0,005 %, collyre en solution                | PL/H/0386/001                       | 35 113                               | ARROW GENERIQUES                          | FR  |
| Latanoprost Arrow 50 microgramos/ml colirio en solución       | PL/H/0386/001                       | 70721                                | ARROW GENERICS LIMITED                    | ES  |
| Latanoprost Arrow, 50 mikrogramów/ml, krople do oczu, roztwór | NO/H/0141/001                       | 15640                                | ACTAVIS GROUP PTC EHF.                    | PL  |
| Latanoprost Aurobindo 50 microgram/ml, oogdruppels, oplossing | PL/H/0386/001                       | RVG 101423                           | AUROBINDO PHARMA B.V.                     | NL  |
| Latanoprost Aurovitas 50 microgramos/ml colirio en solución   | NL/H/1382/001                       | 71.098                               | AUROVITAS SPAIN,S.A.U.                    | ES  |
| LATANOPROST BRUSCHETTINI 50 µg / ml colírio, solução          | PT/H/0544/001                       | 5318746                              | BRUSCHETTINI S.R.L                        | PT  |
| Latanoprost CF 50 microgram/ml oogdruppels, oplossing         | NL/H/1809/001                       | RVG 105910                           | CENTRAFARM B.V.                           | NL  |
| Latanoprost Ciclum 50 microgramas/ml colírio, solução         | NL/H/1809/001                       | 5371117                              | CICLUM FARMA UNIPessoal LDA.              | PT  |
| Latanoprost Ciclum 50 microgramas/ml colírio, solução         | NL/H/1809/001                       | 5371109                              | CICLUM FARMA UNIPessoal LDA.              | PT  |

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| Latanoprost Ciclum 50 microgramas/ml colírio, solução    | NL/H/1809/001                       | NL/H/1809/001                        | CICLUM FARMA UNIPessoal LDA.              | PT  |
| LATANOPROST CINFA 50 MICROGRAMOS/ML COLIRIO EN SOLUCIÓN  | UK/H/2707/001/DC                    | 73959                                | LABORATORIOS CINFA, S.A.                  | ES  |
| Latanoprost Combix 50 microgramas/ml colirio en solución | NL/H/1948/001                       | 75.082                               | LABORATORIOS COMBIX, S.L.U.               | ES  |
| Latanoprost DEMO 50 Mikrogramm/ml Augentropfen, Lösung   | UK/H/5496/001                       | 91614.00.00                          | DEMO S.A.                                 | DE  |
| LATANOPROST EG 0,005 %, collyre en solution              | NL/H/1809/001                       | NL38465                              | EG LABO - LABORATOIRES EUROGENERICS       | FR  |
| Latanoprost EG 50 microgram/ml oogdruppels, oplossing    | NL/H/1809/001                       | BE381525                             | EUROGENERICS SA                           | BE  |
| Latanoprost EG 50 microgrammes/ml collyre en solution    | NL/H/1809/001                       | BE381525                             | EUROGENERICS SA                           | BE  |
| Latanoprost EG 50 microgrammes/ml collyre en solution    | NL/H/1809/001                       | 2012030044                           | EUROGENERICS N.V./S.A.                    | LU  |
| Latanoprost EG 50 Mikrogramm/ml Augentropfen, Lösung     | NL/H/1809/001                       | BE381525                             | EUROGENERICS SA                           | BE  |



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| Latanoprost FDC Pharma<br>50 microgramos/ml<br>colirio en solución       | UK/H/4549/001                       | 76568                                | FDC PHARMA                                | ES  |
| Latanoprost FDC Pharma<br>50 Mikrogramm / ml<br>Augentropfen             | UK/H/4549/001                       | 84694.00.00                          | FDC PHARMA                                | DE  |
| Latanoprost Genoptim,<br>50 mikrogramów/ml,<br>krople do oczu, roztwór   | NL/H/1948/001                       | 19537                                | SYNOPTIS PHARMA SP Z O O                  | PL  |
| Latanoprost HEXAL 50<br>Mikrogramm/ml<br>Augentropfen, Lösung            | DE/H/2075/001                       | 75071.00.00                          | HEXAL AG                                  | DE  |
| Latanoprost Ingen<br>Pharma 50<br>mikrogramų/ml akių lašai<br>(tirpalas) | not available                       | LT/1/12/2933/001                     | SIA INGEN PHARMA                          | LT  |
| Latanoprost Ingen<br>Pharma 50<br>mikrogramų/ml akių lašai<br>(tirpalas) | not available                       | LT/1/12/2933/002                     | SIA INGEN PHARMA                          | LT  |
| Latanoprost Malcosa 50<br>Mikrogramm/ml<br>Augentropfen                  | DE/H/1999/001                       | 75006.00.00                          | MALCOSA LTD                               | DE  |
| Latanoprost Medical Mix<br>50 microgramos/ml<br>colirio en solución      | not available                       | 73520                                | MEDICAL MIX S.L.                          | ES  |

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|---|-------------------------------------|--------------------------------------|---|---|
| Latanoprost Mylan 0,05 mg/ml colírio, solução           | SE/H/1283/001                       | 5630546                              | MYLAN, LDA                                | PT  |
| Latanoprost Mylan 0,05 mg/ml colírio, solução           | SE/H/1283/001                       | 5630538                              | MYLAN, LDA                                | PT  |
| Latanoprost Mylan 0,05 mg/ml colírio, solução           | SE/H/1283/001                       | 5630553                              | MYLAN, LDA                                | PT  |
| Latanoprost Mylan 0,05 mg/ml oční kapky, roztok         | SE/H/1283/001                       | 64/294/14-C                          | GENERICS [UK] LIMITED                     | CZ  |
| Latanoprost Mylan 0,05 mg/ml, oogdruppels, oplossing    | SE/H/1283/001                       | RVG 113160                           | MYLAN B.V.                                | NL  |
| Latanoprost Mylan 50 microgrammi/ml collirio, soluzione | SE/H/1283/001                       | 042620017                            | MYLAN S.P.A.                              | IT  |
| Latanoprost Mylan 50 microgrammi/ml collirio, soluzione | SE/H/1283/001                       | 042620029                            | MYLAN S.P.A.                              | IT  |
| Latanoprost Mylan 50 microgrammi/ml collirio, soluzione | SE/H/1283/001                       | 042620031                            | MYLAN S.P.A.                              | IT  |
| Latanoprost Mylan 50 mikrogram/ml øyedråper, oppløsning | SE/H/1283/001                       | 13-9428                              | MYLAN AB                                  | NO  |

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|---|-------------------------------------|--------------------------------------|---|---|
| Latanoprost Mylan 50 mikrogram/ml, ögondroppar, lösning     | SE/H/1283/001                       | 48953                                | MYLAN AB                                  | SE  |
| Latanoprost Mylan 50 mikrógrömm/ml augndropar, lausn        | SE/H/1283/001                       | IS/1/14/041/01                       | MYLAN AB                                  | IS  |
| Latanoprost Noridem 50 microgrammes/mL, collyre en solution | UK/H/5496/001                       | BE508951                             | NORIDEM ENTERPRISES LTD                   | BE  |
| Latanoprost NTC 50 microgram/ml, oogdruppels, oplossing     | NL/H/1876/001                       | RVG 106488                           | NTC SRL                                   | NL  |
| LATANOPROST NTC 50 microgrammi/ml collirio, soluzione       | NL/H/1876/001                       | 041375015                            | NTC SRL                                   | IT  |
| LATANOPROST NTC 50 microgrammi/ml collirio, soluzione       | NL/H/1876/001                       | 041375027                            | NTC SRL                                   | IT  |
| LATANOPROST NTC 50 microgrammi/ml collirio, soluzione       | NL/H/1876/001                       | 041375039                            | NTC SRL                                   | IT  |
| Latanoprost NTC 50 mikrogrami/ml acu pilieni, šķīdums       | NL/H/1876/001                       | 11-0323                              | NTC SRL                                   | LV  |
| Latanoprost NTC 50 mikrogramų/ml akių lašai, tirpalas       | NL/H/1876/001                       | LT/1/11/2686/002                     | NTC SRL                                   | LT  |

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| Latanoprost NTC 50 mikrogramų/ml akių lašai, tirpalas         | NL/H/1876/001                       | LT/1/11/2686/003                     | NTC SRL                                   | LT  |
| Latanoprost NTC 50 mikrogramų/ml akių lašai, tirpalas         | NL/H/1876/001                       | LT/1/11/2686/001                     | NTC SRL                                   | LT  |
| Latanoprost Pfizer 0,05 mg/ml oldatos szemcsepp               | not available                       | OGYI-T-21936/01                      | PFIZER KFT.                               | HU  |
| Latanoprost Pfizer 0,05 mg/ml oldatos szemcsepp               | not available                       | OGYI-T-21936/02                      | PFIZER KFT.                               | HU  |
| Latanoprost Ranbaxy 50 microgram/ml oogdruppels, oplossing    | NL/H/2052/001                       | RVG 107731                           | RANBAXY (UK) LIMITED                      | NL  |
| LATANOPROST RANBAXY 50 microgrammes/ml, collyre en solution   | NL/H/2052/001                       | NL 40087                             | RANBAXY PHARMACIE GENERIQUES              | FR  |
| Latanoprost ratiopharm 50 mikrog/ml silmatipat, liuos         | NO/H/0139/001                       | 24330                                | RATIOPHARM GMBH                           | FI  |
| Latanoprost ratiopharm 50 mikrogram/ml, øyedråper, oppløsning | NO/H/0139/001                       | 07-5388                              | RATIOPHARM GMBH                           | NO  |
| Latanoprost ratiopharm 50 Mikrogramm/ml Augentropfen          | NO/H/0139/001                       | 1-28392                              | RATIOPHARM ARZNEIMITTEL VERTRIEBS-GMBH    | AT  |

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|--|-------------------------------------|--------------------------------------|---|---|
| Latanoprost Sandoz 0,05 mg/ml oogdruppels, oplossing       | DE/H/2076/001                       | BE393985                             | SANDOZ N.V.                               | BE  |
| Latanoprost Sandoz 0,05 mg/ml, oogdruppels, oplossing      | DE/H/2076/001                       | RVG 104079                           | SANDOZ B.V.                               | NL  |
| LATANOPROST SANDOZ 50 microgrammes/ml, collyre en solution | DE/H/2076/001                       | 34009 219 375 3 4                    | SANDOZ                                    | FR  |
| LATANOPROST SANDOZ 50 microgrammes/ml, collyre en solution | DE/H/2076/001                       | 34009 219 377 6 3                    | SANDOZ                                    | FR  |
| LATANOPROST SANDOZ 50 microgrammes/ml, collyre en solution | DE/H/2076/001                       | 34009 219 378 2 4                    | SANDOZ                                    | FR  |
| Latanoprost Sandoz 50 microgramos/ml colirio en solución   | DE/H/2076/001                       | 74523                                | SANDOZ FARMACÉUTICA, S.A.                 | ES  |
| Latanoprost Sandoz 50 mikrog/ml silmätipat, liuos          | DE/H/2076/001                       | 27104                                | SANDOZ A/S                                | FI  |
| Latanoprost Sandoz 50 mikrogram/ml ögondroppar, lösning    | DE/H/2076/001                       | 41820                                | SANDOZ A/S                                | SE  |
| Latanoprost Sandoz 50 mikrogram/ml øyedråper, oppløsning.  | DE/H/2076/001                       | 08-6413                              | SANDOZ A/S                                | NO  |

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|---|-------------------------------------|--------------------------------------|---|---|
| Latanoprost Sandoz 50 Mikrogramm/ml - Augentropfen                | DE/H/2076/001                       | 1-30546                              | SANDOZ GMBH                               | AT  |
| Latanoprost STADA 50 microgram/ml oogdruppels, oplossing          | NL/H/1810/001                       | RVG 105912                           | STADA ARZNEIMITTEL AG                     | NL  |
| Latanoprost STADA 50 microgramos/ml colirio en solución           | NL/H/1408/001                       | 71103                                | LABORATORIO STADA, S.L.                   | ES  |
| Latanoprost STADA 50 mikrogram/ml, ögondroppar, lösning           | NL/H/1809/001                       | 43052                                | STADA ARZNEIMITTEL AG                     | SE  |
| Latanoprost STADA 50 Mikrogramm/ml Augentropfen                   | NL/H/1809/001                       | 1-30255                              | STADA ARZNEIMITTEL GMBH                   | AT  |
| Latanoprost STADA 50 mikrogramů/ml oční kapky, roztok             | NL/H/3195/001                       | 64/382/15-C                          | STADA ARZNEIMITTEL AG                     | CZ  |
| Latanoprost STADA HF 50 micrograme/ml picături oftalmice, soluție | NL/H/1809/001                       | 5786/2013/01                         | STADA HEMOFARM S.R.L.                     | RO  |
| Latanoprost STADA HF 50 micrograme/ml picături oftalmice, soluție | NL/H/1809/001                       | 5786/2013/02                         | STADA HEMOFARM S.R.L.                     | RO  |
| Latanoprost STADA HF 50 micrograme/ml picături oftalmice, soluție | NL/H/1809/001                       | 5786/2013/03                         | STADA HEMOFARM S.R.L.                     | RO  |

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|---|------------------------------|-------------------------------|--|--|
| Latanoprost STADA, 50 mikrogramów/ml, krople do oczu, roztwór | NL/H/1809/001                | 18283                         | STADA ARZNEIMITTEL AG                    | PL                                       |
| Latanoprost STADA® 50 Mikrogramm/ml Augentropfen              | NL/H/1809/001                | 79707.00.00                   | STADAPHARM GMBH                          | DE                                       |
| Latanoprost TARBIS 50 microgramos/ml colirio en solución      | NL/H/1876/001                | 75539                         | TARBIS FARMA, S.L.                       | ES                                       |
| Latanoprost Teva  | NO/H/0139/001                | 42427                         | TEVA DENMARK A/S                         | DK                                       |
| Latanoprost Teva 50 microgramas/ml colírio, solução           | NO/H/0139/001                | 5436647                       | TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA | PT                                       |
| Latanoprost Teva 50 microgramos/ml colirio en solución        | NO/H/0139/001                | 71221                         | TEVA PHARMA S.L.U                        | ES                                       |
| Latanoprost Teva 50 micrograms/ml eye drop solution           | NO/H/0139/001                | PA0749/173/001                | TEVA PHARMA B.V.                         | IE                                       |
| Latanoprost Teva 50 µg/ml, oogdruppels, oplossing             | NO/H/0139/001                | RVG 101418                    | TEVA NEDERLAND B.V.                      | NL                                       |
| Latanoprost Teva, 50 mikrogram/ml ögondroppar, lösning        | NO/H/0139/001                | 26305                         | TEVA SWEDEN AB                           | SE                                       |

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|---|------------------------------|-------------------------------|------------------------------------|--|
| Latanoprost TRB 50 Mikrogramm/ml Augentropfen                 | DE/H/4788/001/DC             | 84610.00.00                   | TRB CHEMEDICA AG                   | DE                                       |
| Latanoprost-POS 50 microgram/ml, oogdruppels, oplossing       | NL/H/1875/001                | RVG 106487                    | URSAPHARM BENELUX B.V.             | NL                                       |
| Latanoprost-ratiopharm 50 Mikrogramm/ml Augentropfen          | NO/H/0139/001                | 71970.00.00                   | RATIOPHARM GMBH                    | DE                                       |
| Latanoprost-ratiopharm 50 mikrogramu/ml acu pilieni, šķīdums  | NO/H/0139/001                | 09-0121                       | RATIOPHARM GMBH                    | LV                                       |
| Latanoprost-ratiopharm 50 mikrogramų/ml akių lašai (tirpalas) | NO/H/0139/001                | LT/1/09/1544/001              | RATIOPHARM GMBH                    | LT                                       |
| Latanoprost-ratiopharm 50 mikrogramų/ml akių lašai (tirpalas) | NO/H/0139/001                | LT/1/09/1544/002              | RATIOPHARM GMBH                    | LT                                       |
| Latanoprost-ratiopharm 50 mikrogramų/ml akių lašai (tirpalas) | NO/H/0139/001                | LT/1/09/1544/003              | RATIOPHARM GMBH                    | LT                                       |
| Latanoprost-ratiopharm 50 µg/ml Oční kapky, roztok            | NO/H/0139/001                | 64/237/09-C                   | RATIOPHARM GMBH                    | CZ                                       |
| Latanoprost-ratiopharm, 50 mikrogrammi/ml silmatilgad, lahus  | NO/H/0139/001                | 626609                        | RATIOPHARM GMBH                    | EE                                       |



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|--|------------------------------|-------------------------------|------------------------------------|--|
| Latanoprost-ratiopharm®<br>50 Mikrogramm/ml<br>Augentropfen        | NO/H/0139/001                | 0687/10040028                 | RATIOPHARM GMBH                    | LU                                       |
| Latanostad 50<br>microgram/ml<br>oogdruppels, oplossing            | NL/H/3195/001                | RVG 115407                    | STADA ARZNEIMITTEL AG              | NL                                       |
| Latanostill Latanoprost<br>50microgrammi/ml<br>collirio, soluzione | PT/H/0544/001                | 042281016/M                   | BRUSCHETTINI S.R.L                 | IT                                       |
| Latano-Vision 50<br>Mikrogramm/ml<br>Augentropfen, Lösung          | AT/H/0450/001/DC             | 1-30741                       | OMNIVISION GMBH                    | AT                                       |
| Latano-Vision 50<br>Mikrogramm/ml<br>Augentropfen, Lösung          | AT/H/0450/001/DC             | 82805.00.00                   | OMNIVISION GMBH                    | DE                                       |
| Latop 50 microgram/ml<br>eye drops, solution                       | DE/H/2075/001                | PA 711/177/1                  | ROWEX LTD                          | IE                                       |
| Oftastad 50 mikrog/ml<br>silmatipat, liuos                         | NL/H/1809/001                | 27906                         | STADA ARZNEIMITTEL AG              | FI                                       |
| Optopress 50<br>microgram/ml,<br>oogdruppels, oplossing            | NL/H/1948/001                | RVG 106489                    | NTC SRL                            | NL                                       |
| PHARMAPROST<br>50microgram/ml<br>οφθαλμικές σταγόνες<br>διάλυμα    | DE/H/1999/001                | 12137/3-2-14                  | PHARMEX S.A.                       | GR                                       |

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|--|------------------------------|-------------------------------|------------------------------------|--|
| Polprost, 50 mikrogramów/ml, krople do oczu, roztwór       | DE/H/2076/001                | 18344                         | SANDOZ GMBH                        | PL                                       |
| Proxal Actavis 50 µg/ml eye drops, solution                | PL/H/0386/001                | PA 1380/161/1                 | ACTAVIS GROUP PTC EHF.             | IE                                       |
| Rozaprost Mono, 50 mikrogramów/mL, krople do oczu, roztwór | NL/H/2589/001                | 21703                         | ADAMED                             | PL                                       |
| SifiTan 50 micrograme/ml picături oftalmice, soluție       | NL/H/1876/001                | 3903/2011/01                  | NTC SRL                            | RO                                       |
| SifiTan 50 micrograme/ml picături oftalmice, soluție       | NL/H/1876/001                | 3903/2011/02                  | NTC SRL                            | RO                                       |
| SifiTan 50 micrograme/ml picături oftalmice, soluție       | NL/H/1876/001                | 3903/2011/03                  | NTC SRL                            | RO                                       |
| XALATAN 0,005 % Augentropfen, Lösung                       | UK/H/0179/001                | BE183967                      | PFIZER S.A. (BELGIUM)              | BE                                       |
| XALATAN 0,005 % Augentropfen, Lösung                       | UK/H/0179/001                | 2009060447                    | PFIZER S.A. (BELGIUM)              | LU                                       |
| Xalatan 0,005% akių lašai (tirpalas)                       | not available                | LT/1/99/0417/001              | PFIZER EUROPE MA EEIG              | LT                                       |

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|--|------------------------------|-------------------------------|------------------------------------|--|
| Xalatan 0,05 mg/ml oldatos szemcsepp           | not available                | OGYI-T-5637/01                | PFIZER KFT.                        | HU                                       |
| Xalatan 0,05 mg/ml oldatos szemcsepp           | not available                | OGYI-T- 5637/02               | PFIZER KFT.                        | HU                                       |
| XALATAN 50 µg/1 ml očná roztoková instilácia   | not available                | 64/0121/98-S                  | PFIZER EUROPE MA EEIG              | SK                                       |
| XALATAN 50 microgram/ml oogdruppels, oplossing | UK/H/0179/001                | BE183967                      | PFIZER S.A. (BELGIUM)              | BE                                       |
| Xalatan 50 microgramas/ml colírio, solução     | UK/H/0179/001                | 5226840                       | LABORATÓRIOS PFIZER, LDA.          | PT                                       |
| Xalatan 50 microgramas/ml colírio, solução     | UK/H/0179/001                | 2547388                       | LABORATÓRIOS PFIZER, LDA.          | PT                                       |
| Xalatan 50 microgramas/ml colírio, solução     | UK/H/0179/001                | 5226857                       | LABORATÓRIOS PFIZER, LDA.          | PT                                       |
| Xalatan 50 microgramas/ml colírio, solução     | UK/H/0179/001                | 5226832                       | LABORATÓRIOS PFIZER, LDA.          | PT                                       |
| Xalatan 50 microgramas/ml colírio, solução     | UK/H/0179/001                | 2547487                       | LABORATÓRIOS PFIZER, LDA.          | PT                                       |

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|--|-------------------------------------|--------------------------------------|---|---|
| Xalatan 50 micrograme/ml picături oftalmice, soluție | not available                       | 7107/2014/02                         | PFIZER EUROPE MA EEIG                     | RO  |
| Xalatan 50 micrograme/ml picături oftalmice, soluție | not available                       | 7107/2014/04                         | PFIZER EUROPE MA EEIG                     | RO  |
| Xalatan 50 micrograme/ml picături oftalmice, soluție | not available                       | 7107/2014/01                         | PFIZER EUROPE MA EEIG                     | RO  |
| Xalatan 50 micrograme/ml picături oftalmice, soluție | not available                       | 7107/2014/03                         | PFIZER EUROPE MA EEIG                     | RO  |
| XALATAN 50 microgrammes/ml collyre en solution       | UK/H/0179/001                       | BE183967                             | PFIZER S.A. (BELGIUM)                     | BE  |
| XALATAN 50 microgrammes/ml collyre en solution       | UK/H/0179/001                       | 2009060447                           | PFIZER S.A. (BELGIUM)                     | LU  |
| XALATAN 50 microgrammes/ml, collyre en solution      | UK/H/0179/001                       | 34009 343840 6 6                     | PFIZER HOLDING FRANCE                     | FR  |
| XALATAN 50 microgrammes/ml, collyre en solution      | UK/H/0179/001                       | 34009 343841 2 7                     | PFIZER HOLDING FRANCE                     | FR  |
| XALATAN 50 microgrammi/ml collirio, soluzione        | UK/H/0179/001                       | 033219027                            | PFIZER ITALIA S.R.L.                      | IT  |

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|---|-------------------------------------|--------------------------------------|---|---|
| XALATAN 50<br>microgrammi/ml collirio,<br>soluzione | UK/H/0179/001                       | 033219015                            | PFIZER ITALIA S.R.L.                      | IT  |
| XALATAN 50<br>microgrammi/ml collirio,<br>soluzione | UK/H/0179/001                       | 033219027                            | PFIZER ITALIA S.R.L.                      | IT  |
| XALATAN 50<br>microgrammi/ml collirio,<br>soluzione | UK/H/0179/001                       | 033219015                            | PFIZER ITALIA S.R.L.                      | IT  |
| Xalatan 50<br>microgramos/ml colirio<br>en solución | UK/H/0179/001                       | 61.756                               | PFIZER, S.L.                              | ES  |
| Xalatan 50<br>micrograms/ml eye<br>drops, solution  | UK/H/0179/001                       | PA 822/140/1                         | PFIZER HEALTHCARE<br>IRELAND              | IE  |
| Xalatan 50<br>micrograms/ml eye<br>drops, solution  | not available                       | MA505/02501                          | PFIZER HELLAS, A.E.                       | MT  |
| Xalatan 50<br>micrograms/ml eye<br>drops, solution  | UK/H/0179/001                       | PL 00057/1057                        | PFIZER LIMITED                            | UK  |
| Xalatan 50 mikróg/ml<br>augndropar, lausn           | not available                       | 980195                               | PFIZER APS                                | IS  |
| Xalatan 50 mikrog/ml<br>ögondroppar, lösning        | UK/H/0179/001                       | 12694                                | PFIZER OY                                 | FI  |

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|--|------------------------------|-------------------------------|------------------------------------|--|
| Xalatan 50 mikrog/ml<br>øyedråper, oppløsning                      | not available                | 95-2153                       | PFIZER AS                          | NO                                       |
| Xalatan 50 mikrog/ml<br>silmlätipat, liuos                         | UK/H/0179/001                | 12694                         | PFIZER OY                          | FI                                       |
| Xalatan 50<br>mikrogram/ml,<br>ögondroppar, lösning                | not available                | 12716                         | PFIZER AB                          | SE                                       |
| XALATAN 50<br>mikrograma/ml kapi za<br>oko, otopina                | not available                | UP/I-530-09/11-02/198         | PFIZER CROATIA D.O.O.              | HR                                       |
| Xalatan 50<br>mikrogrami/ml acu<br>pilieni, šķīdums                | not available                | 00-0502                       | PFIZER EUROPE MA EEIG              | LV                                       |
| Xalatan 50<br>mikrogramov/ml kapljice<br>za oko, raztopina         | not available                | H/98/01669/001                | PFIZER LUXEMBOURG SARL             | SI                                       |
| Xalatan 50<br>μικρογραμμάρια/ml<br>οφθαλμικές σταγόνες,<br>διάλυμα | UK/H/0179/001                | 20805                         | PFIZER HELLAS, A.E.                | CY                                       |
| Xalatan 50<br>μικρογραμμάρια/ml<br>οφθαλμικές σταγόνες,<br>διάλυμα | UK/H/0179/001                | 32620/07/11-04-2008           | PFIZER HELLAS, A.E.                | GR                                       |
| XALATAN Oční<br>kapky, roztok                                      | not available                | 64/164/99-C                   | PFIZER, SPOL. S R.O.               | CZ                                       |

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|---|-------------------------------------|--------------------------------------|---|---|
| Xalatan, 50 mikrogrammi/ml silmatilgad, lahus                                       | not available                       | 284899                               | PFIZER EUROPE MA EEIG                             | EE  |
| Xalatan, 50 µg/ml, krople do oczu, roztwór  | not available                       | 4118                                 | PFIZER EUROPE MA EEIG                             | PL  |
| Xalatan, øjendråber, opløsning  | UK/H/0179/001                       | 18752                                | PFIZER APS  | DK  |
| Xalatan, oogdruppels, 50 microgram/ml   | UK/H/0179/001                       | RVG 21304                            | PFIZER B.V.                                       | NL  |
| Xalatan® 50 Mikrogramm/ml Augentropfen  | UK/H/0179/001                       | 1-22019                              | PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.    | AT  |
| Xalatan® 50 Mikrogramm/ml Augentropfen Augentropfen, Lösung                         | UK/H/0179/001                       | 40466.00.00                          | PFIZER PHARMA PFE GMBH                            | DE  |
| Xalmono 0,05 mg/ml oogdruppels, oplossing in verpakking voor éénmalig gebruik       | NL/H/3193/001                       | RVG 115290                           | GENETIC SPA                                       | NL  |
| Xaloptic Free, 50 mikrogramów/ml, krople do oczu, roztwór w pojemniku jednodawkowym | NL/H/3193/001                       | 22424                                | ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA | PL  |

| 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 |
|--|------------------------------|-------------------------------|--|--|
| XALOST 50<br>microgrammi/ml collirio,<br>soluzione       | DE/H/1999/001                | 039795012                     | FARMIGEA SPA                                       | IT                                       |
| XALOST 50<br>microgrammi/ml collirio,<br>soluzione       | DE/H/1999/001                | 039795024                     | FARMIGEA SPA                                       | IT                                       |
| XALOST 50<br>microgrammi/ml collirio,<br>soluzione       | DE/H/1999/001                | 039795036                     | FARMIGEA SPA                                       | IT                                       |
| ZAKOPROST® 0,005%<br>w/v οφθαλμικές σταγόνες<br>διάλυμα. | not available                | 46828/ 25-09-2013             | PHARMAZAC SA                                       | GR                                       |
| Акистан 50<br>микрограма/ml капки за<br>очи, разтвор     | SE/H/1095/001                | 20130062                      | PHARMASELECT<br>INTERNATIONAL<br>BETEILIGUNGS GMBH | BG                                       |
| Ксалатан 50<br>микрограма/ml капки за<br>очи, разтвор    | not available                | 9900241                       | PFIZER ENTERPRISES SARL                            | BG                                       |
| ЛАТАЛУКС 50<br>микрограма/ml капки за<br>очи, разтвор    | NL/H/1654/001                | 20100633                      | PHARMASWISS ČESKÁ<br>REPUBLIKA S.R.O.              | BG                                       |