



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

5 May 2017  
EMA/288255/2017  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: pilocarpine (ophthalmic formulation)

Procedure no.: PSUSA/00002410/201608



| 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 |
|---|------------------------------|-------------------------------|---|--|
| Pilocarpina Farmigea 2% collirio 10 ml                                  | not available                | 004961013                     | FARMIGEA SPA                              | IT                                       |
| PILOCARPINA FARMIGEA 2% COLLIRIO, SOLUZIONE                             | not available                | 004961049                     | FARMIGEA SPA                              | IT                                       |
| PILOCARPINE 2 POUR CENT FAURE, collyre en solution en récipient unidose | not available                | 11776-3400932419685           | LABORATOIRES EUROPHTA                     | FR                                       |
| Isopto Carpine 20 mg/ml augndropar, lausn                               | not available                | 681057IS                      | SA ALCON-COUVREUR NV                      | IS                                       |
| Isopto-Pilokarpin 2 % ögondroppar, lösning                              | not available                | 7338                          | SA ALCON-COUVREUR NV                      | SE                                       |
| Isopto Carpine 40 mg/ml augndropar, lausn                               | not available                | 681058IS                      | SA ALCON-COUVREUR NV                      | IS                                       |
| Isopto Carpine 20 mg/ml silmätipat, liuos                               | not available                | 756                           | SA ALCON-COUVREUR NV                      | FI                                       |
| Isopto Carpine 40 mg/ml silmätipat, liuos                               | not available                | 757                           | SA ALCON-COUVREUR NV                      | FI                                       |
| MINIMS PILOCARPINENITRAAT 20 mg/ml, oogdruppels, oplossing              | not available                | RVG 09368                     | BAUSCH & LOMB PHARMA                      | NL                                       |
| Pilomann® 2 %   | not available                | 6249656.01.00                 | DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH | DE                                       |
| Pilomann® 1 %   | not available                | 6249656.02.00                 | DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH | DE                                       |

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| Pilomann® 0,5 %  | not available                | 6249656.03.00                 | DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH | DE                                       |
| Pilomann®-Öl 2 %   | not available                | 6249627.00.00                 | DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH | DE                                       |
| Pilocarpina Cloridrato Allergan 10 mg/ml collirio, soluzione | not available                | 000248031                     | ALLERGAN S.P.A.                           | IT                                       |
| Pilocarpina Cloridrato Allergan 20 mg/ml collirio, soluzione | not available                | 000248056                     | ALLERGAN S.P.A.                           | IT                                       |
| ISOPTO CARPINE 1% Augentropfen                               | not available                | BE038692                      | ALCON NV                                  | BE                                       |
| ISOPTO CARPINE 2% Augentropfen                               | not available                | BE038717                      | ALCON NV                                  | BE                                       |
| ISOPTO CARPINE 3% Augentropfen                               | not available                | BE118736                      | ALCON NV                                  | BE                                       |
| ISOPTO CARPINE 4% Augentropfen                               | not available                | BE038735                      | ALCON NV                                  | BE                                       |
| ISOPTO CARPINE 1% Augentropfen                               | not available                | 2005098229                    | ALCON NV                                  | LU                                       |
| ISOPTO CARPINE 2% Augentropfen                               | not available                | 2005098230                    | ALCON NV                                  | LU                                       |
| ISOPTO CARPINE 3% collyre en solution                        | not available                | BE118736                      | ALCON NV                                  | BE                                       |
| ISOPTO CARPINE 3% oogdruppels, oplossing                     | not available                | BE118736                      | ALCON NV                                  | BE                                       |

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|--|-------------------------------------|--------------------------------------|---|---|
| ISOPTO CARPINE 1% collyre en solution          | not available                       | 2005098229                           | ALCON NV                                  | LU  |
| ISOPTO CARPINE 1% collyre en solution          | not available                       | BE038692                             | ALCON NV                                  | BE  |
| ISOPTO CARPINE 1% oogdruppels, oplossing       | not available                       | BE038692                             | ALCON NV                                  | BE  |
| ISOPTO-PILOCARPINE 2 % collyre                 | not available                       | VNL 8427                             | LABORATOIRES ALCON S.A.S                  | FR  |
| ISOPTO CARPINE 2% collyre en solution          | not available                       | BE038717                             | ALCON NV                                  | BE  |
| ISOPTO CARPINE 4% collyre en solution          | not available                       | BE038735                             | ALCON NV                                  | BE  |
| ISOPTO CARPINE 4% oogdruppels, oplossing       | not available                       | BE038735                             | ALCON NV                                  | BE  |
| ISOPTO CARPINE 2% oogdruppels, oplossing       | not available                       | BE038717                             | ALCON NV                                  | BE  |
| ISOPTO-PILOCARPINE 1 % collyre                 | not available                       | VNL 8428                             | LABORATORIES ALCON S.A.                   | FR  |
| ISOPTO-PILOCARPINE 0,5% collyre                | not available                       | VNL 10 802                           | LABORATOIRES ALCON S.A.S                  | FR  |
| ISOPTO CARPINE® 4%                             | not available                       | 46845/18-9-2009                      | ALCON LABORATORIES HELLAS S.A.            | GR  |
| ISOPTO CARPINE® 2%                             | not available                       | 46844/18-9-2009                      | ALCON LABORATORIES HELLAS S.A.            | GR  |
| ISOPTO CARPINE 2% collyre en solution          | not available                       | 2005098230                           | ALCON NV                                  | LU  |

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| PILOCARPINE 1 POUR CENT FAURE, collyre en solution en récipient unidose | not available                       | 11777-3400932419456                  | LABORATOIRES EUROPHTA                     | FR  |
| DROPILTON 2%  | not available                       | 004897017                            | BRUSCHETTINI S.R.L                        | IT  |
| DROPILTON 4%  | not available                       | 004897029                            | BRUSCHETTINI S.R.L                        | IT  |
| Minims Pilocarpine Nitrate 2%w/v Eye Drops, Solution                    | not available                       | PL 03468/0078                        | BAUSCH & LOMB UK LTD.                     | UK  |
| Pilocarpina Cloridrato Allergan 10 mg/ml collirio, soluzione            | not available                       | 000248031                            | ALLERGAN S.P.A.                           | IT  |
| Pilocarpina Cloridrato Allergan 20 mg/ml collirio, soluzione            | not available                       | 000248056                            | ALLERGAN S.P.A.                           | IT  |
| Isopto-Pilokarpin 4 % ögondroppar, lösning                              | not available                       | 7340                                 | SA ALCON-COUVREUR NV                      | SE  |
| DROPILTON 2%  | not available                       | 004897017                            | BRUSCHETTINI S.R.L                        | IT  |
| DROPILTON 4%  | not available                       | 004897029                            | BRUSCHETTINI S.R.L                        | IT  |
| Pilokarpin Minims 20 mg/ml øyedråper, oppløsning                        | not available                       | 5734                                 | BAUSCH & LOMB UK LTD.                     | NO  |
| Minims Pilocarpine Nitrate 2% w/v, Eye Drops, Solution                  | not available                       | PA0555/022/001                       | BAUSCH & LOMB UK LTD.                     | IE  |