



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

8 March 2018  
EMA/154207/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: ketorolac (ophtalmic formulations)

Procedure no.: PSUSA/00001810/201707



| <b>Product Name (in authorisation country)</b> | <b>MRP / DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| ACULAR 0,5 POUR CENT, collyre                  | not available                         | NL 16248                             | ALLERGAN FRANCE                           | FR                                              |
| ACULAR 0,5% Augentropfen                       | IE/H/0101/001                         | 1-21783                              | ALLERGAN PHARMACEUTICALS IRELAND          | AT                                              |
| ACULAR 0,5% p/v collirio, soluzione            | IE/H/0101/001                         | 033222023                            | ALLERGAN S.P.A.                           | IT                                              |
| ACULAR 0,5% p/v collirio, soluzione            | IE/H/0101/001                         | 033222035                            | ALLERGAN S.P.A.                           | IT                                              |
| ACULAR 0.5% w/v Eye drops, solution            | IE/H/0101/001                         | PA 148/57/1                          | ALLERGAN PHARMACEUTICALS IRELAND          | IE                                              |
| Acular 0.5% w/v, οφθαλμικές σταγόνες, διάλυμα  | not available                         | 89597/12-12-2013                     | ALLERGAN PHARMACEUTICALS IRELAND          | GR                                              |
| Acular 0.5%, oogdruppels, oplossing            | not available                         | RVG 13381                            | ALLERGAN PHARMACEUTICALS IRELAND          | NL                                              |
| ACULAR 5 mg/ml Augentropfen                    | not available                         | 16217.00.00                          | ALLERGAN PHARMACEUTICALS IRELAND          | DE                                              |
| ACULAR 5 mg/ml Colirio en solució              | IE/H/0101/001                         | 61.690                               | ALLERGAN, S.A.U.                          | ES                                              |
| ACULAR 5 mg/ml Colírio, solução                | IE/H/0101/001                         | 2538288                              | ALLERGAN, S.A.U.                          | PT                                              |

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| ACULAR 5 mg/ml Colírio, solução                | IE/H/0101/001                         | 2538387                              | ALLERGAN, S.A.U.                          | PT                                              |
| ACULAR 5 mg/ml Colírio, solução                | IE/H/0101/001                         | 2538486                              | ALLERGAN, S.A.U.                          | PT                                              |
| Acular 5 mg/ml, silmätipat, liuos              | not available                         | 11774                                | ALLERGAN PHARMACEUTICALS IRELAND          | FI                                              |
| ACULAR, 5 mg/ml, krople do oczu, roztwór       | not available                         | 11327                                | ALLERGAN PHARMACEUTICALS IRELAND          | PL                                              |
| Acular, øjendråber, opløsning                  | not available                         | 15754                                | ALLERGAN PHARMACEUTICALS IRELAND          | DK                                              |
| Acular®                                        | not available                         | PL 00426/0082                        | ALLERGAN LTD                              | UK                                              |
| ACULAR® 5 mg/ml ögondroppar, lösning           | not available                         | 11774                                | ALLERGAN PHARMACEUTICALS IRELAND          | FI                                              |
| ACULARE 0,5 % Augentropfen, Lösung             | not available                         | BE153273                             | ALLERGAN PHARMACEUTICALS IRELAND          | BE                                              |
| ACULARE 0,5 % collyre en solution              | not available                         | BE153273                             | ALLERGAN PHARMACEUTICALS IRELAND          | BE                                              |

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| ACULARE 0,5 % collyre en solution                 | not available                         | 2007019157                           | ALLERGAN PHARMACEUTICALS IRELAND          | LU                                              |
| ACULARE 0,5% oogdruppels, oplossing               | not available                         | BE153273                             | ALLERGAN PHARMACEUTICALS IRELAND          | BE                                              |
| Ketorolac trometamol 0.5% w/v eye drops, solution | UK/H/4540/001                         | PL 25298/0068                        | BROWN & BURK UK LIMITED                   | UK                                              |
| KetoVision 5 mg/ml Augentropfen, Lösung           | AT/H/0518/001/DC                      | 1-30636                              | OMNIVISION GMBH                           | AT                                              |
| KetoVision 5 mg/ml Augentropfen, Lösung           | AT/H/0518/001/DC                      | 79179.00.00                          | OMNIVISION GMBH                           | DE                                              |