



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 March 2023  
EMA/134870/2023  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: ketorolac (ophthalmic formulations)

Procedure no.: PSUSA/00001810/202207

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| <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 %<br>Augentropfen                        | IE/H/0101/001                       | 1-21783                              | ABBVIE GMBH                               | AT                                              |
| ACULAR 0,5% p/v collirio,<br>soluzione              | IE/H/0101/001                       | 033222023                            | ALLERGAN S.P.A.                           | IT                                              |
| ACULAR 0,5% p/v collirio,<br>soluzione              | IE/H/0101/001                       | 033222035                            | ALLERGAN S.P.A.                           | IT                                              |
| ACULAR 0,5%, collyre en<br>solution                 | not available                       | 34009 334 295 9 1                    | ALLERGAN FRANCE, TOUR<br>CBX, COURBEVOIE  | FR                                              |
| ACULAR 0.5% w/v Eye<br>drops, solution              | IE/H/0101/001                       | PA1824/15/1                          | ABBVIE LIMITED                            | IE                                              |
| Acular 0.5% w/v,<br>οφθαλμικές σταγόνες,<br>διάλυμα | not available                       | 89597/12-12-2013                     | ALLERGAN<br>PHARMACEUTICALS IRELAND       | GR                                              |
| Acular 0.5%, oogdruppels,<br>oplossing              | not available                       | RVG 13381                            | ABBVIE B.V.                               | NL                                              |
| ACULAR 5 mg/ml<br>Augentropfen                      | not available                       | 16217.00.00                          | ABBVIE DEUTSCHLAND GMBH<br>& CO. KG       | DE                                              |
| ACULAR 5 mg/ml Colirio<br>en solución               | IE/H/0101/001                       | 61.690                               | ABBVIE SPAIN S.L.U.                       | ES                                              |

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| ACULAR 5 mg/ml Colírio, solução                | IE/H/0101/001                       | 2538486                              | ABBVIE, LDA.                              | PT                                              |
| ACULAR 5 mg/ml Colírio, solução                | IE/H/0101/001                       | 2538387                              | ABBVIE, LDA.                              | PT                                              |
| ACULAR 5 mg/ml Colírio, solução                | IE/H/0101/001                       | 2538288                              | ABBVIE, LDA.                              | PT                                              |
| Acular, øjendråber, opløsning                  | not available                       | 15754                                | ABBVIE A/S                                | DK                                              |
| Acular®.                                       | not available                       | PL 41042/0051                        | ABBVIE LTD (UK)                           | XI                                              |
| ACULARE 0,5 % Augentropfen, Lösung             | not available                       | BE153273                             | ABBVIE S.A.                               | BE                                              |
| ACULARE 0,5 % Augentropfen, Lösung             | not available                       | 2007019157                           | ABBVIE S.A.                               | LU                                              |
| ACULARE 0,5 % collyre en solution              | not available                       | BE153273                             | ABBVIE S.A.                               | BE                                              |
| ACULARE 0,5 % collyre en solution              | not available                       | 2007019157                           | ABBVIE S.A.                               | LU                                              |

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| ACULARE 0,5%<br>oogdruppels, oplossing                  | not available                       | BE153273                             | ABBVIE S.A.                               | BE                                              |
| Ketorolac Micro Labs 5<br>mg/ml Augentropfen,<br>Lösung | DE/H/4840/001                       | 139282                               | MICRO LABS GMBH                           | AT                                              |
| Ketorolac Micro Labs 5<br>mg/ml Augentropfen,<br>Lösung | DE/H/4840/001                       | 139282                               | MICRO LABS GMBH                           | AT                                              |
| Ketorolac Micro Labs 5<br>mg/ml Augentropfen,<br>Lösung | DE/H/4840/001                       | 139282                               | MICRO LABS GMBH                           | AT                                              |
| Ketorolac Micro Labs 5<br>mg/ml Augentropfen,<br>Lösung | DE/H/4840/001                       | 139282                               | MICRO LABS GMBH                           | AT                                              |
| Ketorolac Micro Labs 5<br>mg/ml Augentropfen,<br>Lösung | DE/H/4840/001                       | 98578.00.00                          | MICRO LABS GMBH                           | DE                                              |
| Ketorolac Micro Labs 5<br>mg/ml Augentropfen,<br>Lösung | DE/H/4840/001                       | 98578.00.00                          | MICRO LABS GMBH                           | DE                                              |
| Ketorolac Micro Labs 5<br>mg/ml Augentropfen,<br>Lösung | DE/H/4840/001                       | 98578.00.00                          | MICRO LABS GMBH                           | DE                                              |
| Ketorolac Micro Labs 5<br>mg/ml Augentropfen,<br>Lösung | DE/H/4840/001                       | 98578.00.00                          | MICRO LABS GMBH                           | DE                                              |

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| KetoVision 5 mg/ml<br>Augentropfen, Lösung     | AT/H/0518/001                       | 1-30636                              | OMNIVISION GMBH                           | AT                                              |
| KetoVision 5 mg/ml<br>Augentropfen, Lösung     | AT/H/0518/001                       | 79179.00.00                          | OMNIVISION GMBH                           | DE                                              |