



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

31 August 2023  
EMA/397638/2023  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance(s): alitretinoin (oral use)

Procedure No. PSUSA/00010710/202301



| 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 |
|-----------------------------------------|------------------------------|-------------------------------|-----------------------------------------------|------------------------------------------|
| TOCTINO 10 mg Weichkapseln              | DK/H/1377/001                | 1-28037                       | GLAXOSMITHKLINE PHARMA GMBH.                  | AT                                       |
| TOCTINO 30 mg Weichkapseln              | DK/H/1377/002                | 1-28038                       | GLAXOSMITHKLINE PHARMA GMBH.                  | AT                                       |
| Alitrederm 10 mg Weichkapseln           | DE/H/6484/001                | 2200599.00.00                 | DERMAPHARM AG                                 | DE                                       |
| Alitrederm 30 mg Weichkapseln           | DE/H/6484/002                | 2200600.00.00                 | DERMAPHARM AG                                 | DE                                       |
| Toctino 10 mg Weichkapseln              | DK/H/1377/001                | 71216.00.00                   | GLAXOSMITHKLINE GMBH & CO. KG                 | DE                                       |
| Toctino 30 mg Weichkapseln              | DK/H/1377/002                | 71255.00.00                   | GLAXOSMITHKLINE GMBH & CO. KG                 | DE                                       |
| Toctino, bløde kapsler                  | DK/H/1377/001                | 42008                         | STIEFEL LABORATORIES LEGACY (IRELAND) LIMITED | DK                                       |
| Toctino, bløde kapsler                  | DK/H/1377/002                | 42009                         | STIEFEL LABORATORIES LEGACY (IRELAND) LIMITED | DK                                       |
| Toctino 10 mg cápsulas blandas          | DK/H/1377/001                | 70.843                        | GLAXOSMITHKLINE, S.A.                         | ES                                       |
| Toctino 30 mg cápsulas blandas          | DK/H/1377/002                | 70.844                        | GLAXOSMITHKLINE, S.A.                         | ES                                       |
| Toctino 10 mg kapselit, pehmeä          | DK/H/1377/001                | 24078                         | GLAXOSMITHKLINE OY                            | FI                                       |
| Toctino 30 mg kapselit, pehmeä          | DK/H/1377/002                | 24079                         | GLAXOSMITHKLINE OY                            | FI                                       |
| TOCTINO 10 mg, capsule molle            | DK/H/1377/001                | NL34847                       | STIEFEL LABORATORIES LEGACY (IRELAND) LIMITED | FR                                       |
| TOCTINO 30 mg, capsule molle            | DK/H/1377/002                | NL34848                       | STIEFEL LABORATORIES LEGACY (IRELAND) LIMITED | FR                                       |
| Toctino 10 mg mjúk hylki                | DK/H/1377/001                | IS/1/09/077/01                | STIEFEL LABORATORIES LEGACY (IRELAND) LIMITED | IS                                       |
| Toctino 30 mg mjúk hylki                | DK/H/1377/002                | IS/1/09/077/02                | STIEFEL LABORATORIES LEGACY (IRELAND) LIMITED | IS                                       |
| TOCTINO 10 mg capsule molli             | DK/H/1377/001                | 038849016                     | STIEFEL LABORATORIES LEGACY (IRELAND) LIMITED | IT                                       |
| TOCTINO 30 mg capsule                   | DK/H/1377/002                | 038849030                     | STIEFEL LABORATORIES                          | IT                                       |

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|-----------------------------------------|------------------------------|-------------------------------|--------------------------------------------------|------------------------------------------|
| molli                                   |                              |                               | LEGACY (IRELAND) LIMITED                         |                                          |
| Toctino 10 mg, capsules, zacht          | DK/H/1377/001                | RVG 100957                    | STIEFEL LABORATORIES<br>LEGACY (IRELAND) LIMITED | NL                                       |
| Toctino 30 mg, capsules, zacht          | DK/H/1377/002                | RVG 100962                    | STIEFEL LABORATORIES<br>LEGACY (IRELAND) LIMITED | NL                                       |
| Toctino 10 mg myke kapsler              | DK/H/1377/001                | 09-6715                       | STIEFEL LABORATORIES<br>LEGACY (IRELAND) LIMITED | NO                                       |
| Toctino 30 mg myke kapsler              | DK/H/1377/002                | 09-6716                       | STIEFEL LABORATORIES<br>LEGACY (IRELAND) LIMITED | NO                                       |
| TOCTINO kapsulki miekkie 10 mg          | DK/H/1377/001                | 17605                         | STIEFEL LABORATORIES<br>LEGACY (IRELAND) LIMITED | PL                                       |
| TOCTINO kapsułki miękkie 30 mg          | DK/H/1377/002                | 17606                         | STIEFEL LABORATORIES<br>LEGACY (IRELAND) LIMITED | PL                                       |
| TOCTINO 10 mg mehke kapsule             | DK/H/1377/001                | H/10/01534/001                | GLAXOSMITHKLINE<br>TRADING SERVICES<br>LIMITED   | SI                                       |
| TOCTINO 30 mg mehke kapsule             | DK/H/1377/002                | H/10/01534/002                | GLAXOSMITHKLINE<br>TRADING SERVICES<br>LIMITED   | SI                                       |
| Toctino 10 mg mäkké kapsuly             | DK/H/1377/001                | 46/0139/10-S                  | GLAXOSMITHKLINE<br>TRADING SERVICES<br>LIMITED   | SK                                       |
| Toctino 30 mg mäkké kapsuly             | DK/H/1377/002                | 46/0140/10-S                  | GLAXOSMITHKLINE<br>TRADING SERVICES<br>LIMITED   | SK                                       |
| Toctino 10 mg capsules, soft            | DK/H/1377/001                | PL 19494/0252                 | GLAXOSMITHKLINE UK<br>LIMITED                    | XI                                       |
| Toctino 30 mg capsules, soft            | DK/H/1377/002                | PL 19494/0253                 | GLAXOSMITHKLINE UK<br>LIMITED                    | XI                                       |