



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 March 2018
EMA/221456/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): methylaminolevulinate

Procedure No.: PSUSA/00002019/201706



| 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 |
|---|------------------------------|-------------------------------|---|--|
| Metvix 160 mg/g kräm | SE/H/0266/001 | 16796 | GALDERMA NORDIC AB | FI |
| Metvix 160 mg/g Creme | SE/H/0266/001 | 2007119559 | GALDERMA BENELUX B.V. | LU |
| Metvix 160 mg/g κρέμα | SE/H/0266/001 | 535/7-1-2008 | GALDERMA HELLAS S.A. | GR |
| Metvix 160 mg/g cream | SE/H/0266/001 | PA 590/20/1 | GALDERMA (UK) LIMITED | IE |
| Metvix | SE/H/0266/001 | 44/0259/04-S | GALDERMA INTERNATIONAL | SK |
| Metvix 160 mg/g cream | SE/H/0266/001 | PL 10590/0048 | GALDERMA (UK) LIMITED | UK |
| Metvix, creme | SE/H/0266/001 | 32850 | GALDERMA NORDIC AB | DK |
| Metvix 160 mg/g krem | SE/H/0266/001 | IS/1/01/047/01 | GALDERMA NORDIC AB | IS |
| Metvix 160 mg/g crème | SE/H/0266/001 | BE240362 | GALDERMA BENELUX B.V. | BE |
| Metvix® 160 mg/g Creme | SE/H/0266/001 | 1-24668 | GALDERMA INTERNATIONAL | AT |
| Metvix 160 mg/g crème | SE/H/0266/001 | BE240362 | GALDERMA BENELUX B.V. | BE |
| Metvix® 160 mg/g Creme | SE/H/0266/001 | 52867.00.00 | GALDERMA LABORATORIUM GMBH | DE |
| Metvix 160 mg/g Creme | SE/H/0266/001 | BE240362 | GALDERMA BENELUX B.V. | BE |
| Metvix 160 mg/g crema | SE/H/0266/001 | 64.968 | LABORATORIOS GALDERMA, S.A. | ES |
| Metvix,160 mg/g krém | SE/H/0266/001 | 44/185/04-C | GALDERMA INTERNATIONAL | CZ |
| Metvix 160 mg/g emulsiovoide | SE/H/0266/001 | 16796 | GALDERMA NORDIC AB | FI |
| METVIXIA 168 mg/g, crème | not available | 34009 377 198 5 8 | GALDERMA INTERNATIONAL | FR |
| Metvix 160 mg/g crema | SE/H/0266/001 | 035995012 | GALDERMA ITALIA S.P.A. | IT |
| Metvix 160 mg/g crème | SE/H/0266/001 | 2007119559 | GALDERMA BENELUX B.V. | LU |
| Metvix 160 mg/g krem | SE/H/0266/001 | 01-8209 | GALDERMA NORDIC AB | NO |
| Metvix 160 mg/g crème | SE/H/0266/001 | RVG 31130 | GALDERMA BENELUX B.V. | NL |
| Metvix 160 mg/g creme | SE/H/0266/001 | 5262381 | LABORATORIOS GALDERMA SA - SUCURSAL EM PORTUGAL | PT |
| Metvix 160 mg/g kräm | SE/H/0266/001 | 16338 | GALDERMA NORDIC AB | SE |
| Metvix 160 mg/g crema | SE/H/0266/001 | 035995024 | GALDERMA ITALIA S.P.A. | IT |
| Luxerm 160 mg/g Creme | SE/H/1565/001 | 1-36910 | GALDERMA INTERNATIONAL | AT |
| Luxera 160 mg/g kräm | SE/H/1565/001 | 53383 | GALDERMA NORDIC AB | SE |
| Luxera 160 mg/g creme | SE/H/1565/001 | 5682836 | LABORATORIOS GALDERMA SA - SUCURSAL EM PORTUGAL | PT |
| Luxerm 160 mg/g Creme | SE/H/1565/001 | 95903.00.00 | GALDERMA LABORATORIUM GMBH | DE |
| Luxera 160 mg/g crema | SE/H/1565/001 | 044441018 | GALDERMA ITALIA S.P.A. | IT |
| Luxera 160 mg/g crema | SE/H/1565/001 | 81.114 | LABORATORIOS GALDERMA, S.A. | ES |