



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 April 2016
EMA/299945/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: erythromycin / isotretinoin

Procedure no.: PSUSA/00001796/201508



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
ISOTREX ERITROMICINA GEL	UK/H/0251/001	62.797	STIEFEL FARMA, S.A.	ES
Isotrexin 20 mg/g + 0.5 mg/g Gel	not available	S00819	GLAXOSMITHKLINE (CYPRUS) LIMITED	CY
Isotrexin-Gel	UK/H/0251/001	1-22842	GLAXOSMITHKLINE PHARMA GMBH.	AT
ANTIBIOTREX, gel	UK/H/0251/001	NL24091	STIEFEL LABORATORIES (IRELAND) LTD	FR
ISOTREXIN®	UK/H/0251/001	034284012	STIEFEL LABORATORIES (IRELAND) LTD	IT
ISOTREXIN®	UK/H/0251/001	034284024	STIEFEL LABORATORIES (IRELAND) LTD	IT
Isotrexin Gel	UK/H/0251/001	2866283	LABORATORIOS FARMACEUTICOS STIEFEL (PORTUGAL) LTDA	PT
Isotrexin Gel	UK/H/0251/001	2866085	LABORATORIOS FARMACEUTICOS STIEFEL (PORTUGAL) LTDA	PT
Isotrexin Gel	UK/H/0251/001	2866382	LABORATORIOS FARMACEUTICOS STIEFEL (PORTUGAL) LTDA	PT
Isotrexin Gel	UK/H/0251/001	2866481	LABORATORIOS FARMACEUTICOS STIEFEL (PORTUGAL) LTDA	PT
Isotrexin Gel	UK/H/0251/001	2866184	LABORATORIOS FARMACEUTICOS STIEFEL (PORTUGAL) LTDA	PT
Isotrexin Gel	UK/H/0251/001	PL 19494/0068	GLAXOSMITHKLINE UK LIMITED	UK
Isotrexin® Isotretinoin 0,05 %, Erythromycin 2 % Gel	UK/H/0251/001	44412.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Isotrexin (20 mg + 0,5 mg)/g, zel	not available	8767	STIEFEL LABORATORIES (IRELAND) LTD	PL
ISOTREXIN Gel	not available	46/052/03-C	GLAXOSMITHKLINE S.R.O.	CZ
Isotrexin 20 mg/g + 0,5 mg/g gel	not available	5856/2013/01	GLAXOSMITHKLINE (GSK) S.R.L.	RO
Isotrexin	not available	46/0032/04-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	SK
Isotrexin 20 mg/g + 0.5 mg/g Gel	not available	PA 1077/123/001	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Isotrexin 0,5 mg/g+20 mg/g gél	not available	OGYI-T-9556/01	GLAXOSMITHKLINE KFT.	HU