



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 May 2019
EMA/280152/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: erythromycin / isotretinoin, isotretinoin (topical formulations)

Procedure no.: PSUSA/00010487/201808

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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
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
STIEFOTREX	not available	65279/12/02-04-2013	GLAXOSMITHKLINE AEBE	GR
Isotrexin (20 mg + 0,5 mg)/g, zel	not available	8767	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	PL
Isotrex - Gel	not available	1-21786	GLAXOSMITHKLINE PHARMA GMBH.	AT
Isotrex; 500 µg/g, žel	not available	7614	STIEFEL LABORATORIES (IRELAND) LTD	PL
Isotrex Gel 0,05 %	not available	29915.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Isotrexin 20 mg/g + 0,5 mg/g gel	not available	5856/2013/01	GLAXOSMITHKLINE (GSK) S.R.L.	RO
Isotrex, gel	not available	15297	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	DK
Isotrex 0,5 mg/g gel	not available	2219681	LABORATORIOS FARMACEUTICOS STIEFEL (PORTUGAL) LTDA	PT
Isotrex Gel®	not available	PL 19494/0063	GLAXOSMITHKLINE UK LIMITED	UK
Isotrexin 20 mg/g + 0.5 mg/g Gel	not available	PA 1077/123/001	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Isotrex 0.5 mg/g Gel	not available	PA 1077/122/1	GLAXOSMITHKLINE (IRELAND) LIMITED	IE