



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 March 2023
EMA/105133/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): clindamycin phosphate / tretinoin

Procedure no.: PSUSA/00010080/202207



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
Acnatac 10 mg/g + 0,25 mg/g Gel	SE/H/1134/001	1-31861	MYLAN ÖSTERREICH GMBH	AT
Treclinax 10 mg/g + 0,25 mg/g gel	SE/H/1134/001	BE437507	MYLAN EPD BVBA/SPRL	BE
Treclinax 10 mg/g + 0,25 mg/g gel	SE/H/1134/001	BE437507	MYLAN EPD BVBA/SPRL	BE
Treclinax 10 mg/g + 0,25 mg/g Gel	SE/H/1134/001	BE437507	MYLAN EPD BVBA/SPRL	BE
Акнатак 10 mg/g + 0,25 mg/g гел	SE/H/1134/001/DC	20130224	MYLAN EOOD	BG
Acnatac 10 mg/g + 0,25 mg/g γέλη	SE/H/1134/001	021888	MEDA PHARMACEUTICALS S.A.	CY
ACNATAC	SE/H/1134/001	15/202/13-C	MYLAN IRE HEALTHCARE LIMITED	CZ
Acnatac 10mg/g + 0,25mg/g Gel	SE/H/1134/001	85210.00.00	VIATRIS HEALTHCARE GMBH	DE
Acnatac	SE/H/1134/01/DC	48954	VIATRIS APS	DK
Treclinac 10 mg/0,25 mg/g geel	SE/H/1134/001	812213	MEDA PHARMA SIA	EE
TRECLINAC 10 mg/g + 0,25 mg/g Gel	SE/H/1134/001	77.481	MYLAN IRE HEALTHCARE LIMITED	ES
Acnatac 10 mg/g + 0,25 mg/g geeli	SE/H/1134/001	29824	VIATRIS OY	FI
Acnatac 10 mg/g + 0,25 mg/g gel	SE/H/1134/001	29824	VIATRIS OY	FI
ZANEA 10 mg/0,25 mg, gel	SE/H/1134/001	34009 277 382 9 6	MEDA PHARMA SAS	FR
ZANEA 10 mg/0,25 mg, gel	SE/H/1134/001	34009 277 381 2 8	MEDA PHARMA SAS	FR
Acnatac 10 mg/g + 0,25 mg/g γέλη	SE/H/1134/001	41202/17/13-08-2019	MEDA PHARMACEUTICALS S.A.	GR

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Acnex 10mg/g+0,25mg/g gél	SE/H/1134/001	OGYI-T-22460/01	MYLAN EPD KFT.	HU
Acnex 10mg/g+0,25mg/g gél	SE/H/1134/001	OGYI-T-22460/02	MYLAN EPD KFT.	HU
Treclin 1 % / 0.025 % w/w Gel	SE/H/1134/001	PA2010/044/001	MYLAN IRE HEALTHCARE LIMITED	IE
Acnatac 10 mg/g + 0,25 mg/g hlaup	SE/H/1134/001	IS/1/13/032/01	VIATRIS APS	IS
ACNATAC 10 mg/g + 0,25 mg/g gel	SE/H/1134/001	042056022	VIATRIS HEALTHCARE LTD	IT
ACNATAC 10 mg/g + 0,25 mg/g gel	SE/H/1134/001	042056010	VIATRIS HEALTHCARE LTD	IT
Treclinac 10 mg/0,25 mg/g gelis	SE/H/1134/001	LT/1/13/3279/001	MEDA PHARMA SIA	LT
Treclinac 10 mg/0,25 mg/g gelis	SE/H/1134/001	LT/1/13/3279/002	MEDA PHARMA SIA	LT
Treclinax 10 mg/g + 0,25 mg/g gel	SE/H/1134/001	2013/110425	MYLAN EPD BVBA/SPRL	LU
Treclinax 10 mg/g + 0,25 mg/g Gel	SE/H/1134/001	2013/110425	MYLAN EPD BVBA/SPRL	LU
Treclinac 10 mg/ 0,25 mg/g gels	SE/H/1134/001	13-0090	MEDA PHARMA SIA	LV
Treclin 1 %/0.025 % w/w gel	SE/H/1134/001	MA 1187/03001	MYLAN IRE HEALTHCARE LIMITED	MT
Treclinac 0,25 mg/g + 10 mg/g, gel	SE/H/1134/001	RVG 109745	MYLAN HEALTHCARE B.V.	NL
Zalna 10 mg/g/0,25 mg/g gel	SE/H/1134/001	11-8356	VIATRIS AS	NO
Acnatac , (10 mg + 0,25 mg)/g, žel	SE/H/1134/001	21435	MYLAN HEALTHCARE SP. Z.O.O.	PL
Acnatac 10mg/g + 0,25mg/g gel	SE/H/1134/001	5585831	BGP PRODUCTS UNIPESOAL, LDA.	PT
Acnatac 10mg/g + 0,25mg/g gel	SE/H/1134/001	5585823	BGP PRODUCTS UNIPESOAL, LDA.	PT
Acnatac 10 mg/g + 0,25 mg/g gel	SE/H/1134/001	10896/2018/01	VIATRIS HEALTHCARE LTD	RO

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Acnatac 10 mg/g + 0,25 mg/g gel	SE/H/1134/001	10896/2018/02	VIATRIS HEALTHCARE LTD	RO
Acnatac 10 mg/g + 0,25 mg/g gel	SE/H/1134/001	46193	VIATRIS AB	SE
Zalna 10 mg/0,25 mg v 1 g gel	SE/H/1134/001	H/13/01693/001	MEDA PHARMA GMBH & CO. KG	SI
Zalna 10 mg/0,25 mg v 1 g gel	SE/H/1134/001	H/13/01693/002	MEDA PHARMA GMBH & CO. KG	SI
Acnatac 10 mg/g + 0,25 mg/g gél	SE/H/1134/001	46/0464/13-S	VIATRIS HEALTHCARE LTD	SK
Treclin 1 %/0.025 % w/w gel	SE/H/1134/001	PL 46302/0192	MYLAN PRODUCTS LIMITED	XI