



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 December 2016
EMA/77613/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ivermectin (topical use)

Procedure No.: PSUSA/00010376/201604



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
Soolantra	SE/H/1428/001	136170	Galderma International	Austria
Soolantra	SE/H/1428/001	15-0136	Galderma International	Latvia
Soolantra	SE/H/1428/001	20150152	Galderma International	Bulgaria
Soolantra	SE/H/1428/001	22591	Galderma Polska Sp. Z O.O.	Poland
Soolantra	SE/H/1428/001	34009 300 241 0 2 & 34009 300 241 1 9 & 34009 300 241 2 6 & 34009 300 241 4 0	Galderma International	France
Soolantra	SE/H/1428/001	46/0218/15-S	Galderma International	Slovakia
Soolantra	SE/H/1428/001	46/241/15-C	Galderma International	Czech Republic
Soolantra	SE/H/1428/001	51097	Galderma Nordic Ab	Sweden
Soolantra	SE/H/1428/001	54123	Galderma Nordic Ab	Denmark
Soolantra	SE/H/1428/001	5645171	Laboratorios Galderma Sa – Sucursal Em Portugal	Portugal
Soolantra	SE/H/1428/001	79911	Laboratorios Galderma, S.A.	Spain
Soolantra	SE/H/1428/001	872915	Galderma International	Estonia
Soolantra	SE/H/1428/001	92429.00.00	Galderma Laboratorium Gmbh	Germany
Soolantra	SE/H/1428/001	BE 472657	Galderma Benelux B.V.	Belgium
Soolantra	SE/H/1428/001	LT/1/15/3726/001 & LT/1/15/3726/002 & LT/1/15/3726/003 & LT/1/15/3726/004 & LT/1/15/3726/005	Galderma International	Lithuania
Soolantra	SE/H/1428/001	MA117/01101	Galderma International	Malta
Soolantra	SE/H/1428/001	OGYI-T-22822/01 & OGYI-T-22822/02 & OGYI-T-22822/03 & OGYI-T-22822/04 & OGYI-T-22822/05	Galderma International	Hungary
Soolantra	SE/H/1428/001	PA 590/28/1	Galderma (Uk) Limited	Ireland
Soolantra	SE/H/1428/001	PL 10590/0063	Galderma (Uk) Limited	United Kingdom
Soolantra	SE/H/1428/001	RVG 115310	Galderma Benelux B.V.	Netherlands
Soolantra	SE/H/1428/001 & SE/H/1428/001/DC	32238	Galderma Nordic Ab	Finland

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Soolantra	SE/H/1428/001/DC	14-10067	Galderma Nordic Ab	Norway
Soolantra	SE/H/1428/001/DC	7674/2015/01 & 7674/2015/02 & 7674/2015/03 & 7674/2015/04 & 7674/2015/05	Galderma International	Romania
Soolantra	SE/H/1428/001/DC	IS/1/15/048/01	Galderma Nordic Ab	Iceland
Soolantra	SE/H/1428/01/DC		GALDERMA HELIAS SA.	Cyprus
Soolantra	SE/H/1428/01/DC		GALDERMA HELIAS SA.	Greece
Soolantra	SE/H/1428/01/DC		Galderma Italia S.P.A.	Italy