



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 November 2019
EMA/664500/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ivermectin (topical use)

Procedure no.: PSUSA/00010376/201904

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Classified as public by the European Medicines Agency

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 10 mg/g cream	SE/H/1428/001	PL 10590/0063	GALDERMA (UK) LIMITED	UK
Soolantra 10 mg/g krém	SE/H/1428/001	OGYI-T-22822/01	GALDERMA INTERNATIONAL	HU
Soolantra 10 mg/g crème	SE/H/1428/001	BE 472657	GALDERMA BENELUX B.V.	BE
Soolantra 10 mg/g krém	SE/H/1428/001	OGYI-T-22822/02	GALDERMA INTERNATIONAL	HU
Soolantra 10 mg/g krém	SE/H/1428/001	OGYI-T-22822/03	GALDERMA INTERNATIONAL	HU
Soolantra 10 mg/g krém	SE/H/1428/001	OGYI-T-22822/04	GALDERMA INTERNATIONAL	HU
Soolantra 10 mg/g krém	SE/H/1428/001	OGYI-T-22822/05	GALDERMA INTERNATIONAL	HU
Soolantra 10 mg/g crème	SE/H/1428/001	BE 472657	GALDERMA BENELUX B.V.	BE
Soolantra 10 mg/g Creme	SE/H/1428/001	BE 472657	GALDERMA BENELUX B.V.	BE

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 10 mg/g krem	SE/H/1428/001	14-10067	GALDERMA NORDIC AB	NO
Soolantra 10 mg/g creme	SE/H/1428/001	5645171	LABORATORIOS GALDERMA SA – SUCURSAL EM PORTUGAL	PT
Soolantra 10 mg/g cream	SE/H/1428/001	MA117/01101	GALDERMA INTERNATIONAL	MT
Soolantra	SE/H/1428/001	54123	GALDERMA NORDIC AB	DK
Soolantra 10 mg/g kräm	SE/H/1428/001	51097	GALDERMA NORDIC AB	SE
Soolantra 10 mg/g krem	SE/H/1428/001	IS/1/15/048/01	GALDERMA NORDIC AB	IS
Soolantra 10 mg/g cream	SE/H/1428/001	PA 590/28/1	GALDERMA (UK) LIMITED	IE
Soolantra 10 mg/g crème	SE/H/1428/001	RVG 115310	GALDERMA BENELUX B.V.	NL
Soolantra 10 mg/g krém	SE/H/1428/001	46/241/15-C	GALDERMA INTERNATIONAL	CZ

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 10 mg/g emulsiovoide	SE/H/1428/001	32238	GALDERMA NORDIC AB	FI
Soolantra 10 mg/g krēm	SE/H/1428/001	32238	GALDERMA NORDIC AB	FI
Soolantra 10 mg/g kremas	SE/H/1428/001	LT/1/15/3726/001	GALDERMA INTERNATIONAL	LT
Soolantra 10 mg/g Creme	SE/H/1428/001	92429.00.00	GALDERMA LABORATORIUM GMBH	DE
Soolantra 10 mg/g kremas	SE/H/1428/001	LT/1/15/3726/002	GALDERMA INTERNATIONAL	LT
Soolantra 10 mg/g kremas	SE/H/1428/001	LT/1/15/3726/003	GALDERMA INTERNATIONAL	LT
Soolantra 10 mg/g kremas	SE/H/1428/001	LT/1/15/3726/004	GALDERMA INTERNATIONAL	LT
Soolantra 10 mg/g kremas	SE/H/1428/001	LT/1/15/3726/005	GALDERMA INTERNATIONAL	LT
Soolantra 10 mg/g kreem	SE/H/1428/001	872915	GALDERMA INTERNATIONAL	EE

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 10 mg/g krém	SE/H/1428/001	46/0218/15-S	GALDERMA INTERNATIONAL	SK
Efacti 10 mg/g crema	SE/H/1428/001	043463013	GALDERMA ITALIA S.P.A.	IT
Efacti 10 mg/g crema	SE/H/1428/001	043463025	GALDERMA ITALIA S.P.A.	IT
Efacti 10 mg/g crema	SE/H/1428/001	043463037	GALDERMA ITALIA S.P.A.	IT
Efacti 10 mg/g crema	SE/H/1428/001	043463049	GALDERMA ITALIA S.P.A.	IT
Efacti 10 mg/g crema	SE/H/1428/001	043463052	GALDERMA ITALIA S.P.A.	IT
Soolantra 10 mg/g crema	SE/H/1428/001	7674/2015/01	GALDERMA INTERNATIONAL	RO
SOOLANTRA 10 mg/g, crème	SE/H/1428/001	34009 300 241 0 2	GALDERMA INTERNATIONAL	FR
Soolantra 10 mg/g crema	SE/H/1428/001	79911	LABORATORIOS GALDERMA SA	ES

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 10 mg/g krēms	SE/H/1428/001	15-0136	GALDERMA INTERNATIONAL	LV
SOOLANTRA 10 mg/g, crème	SE/H/1428/001	34009 300 241 1 9	GALDERMA INTERNATIONAL	FR
SOOLANTRA 10 mg/g, crème	SE/H/1428/001	34009 300 241 2 6	GALDERMA INTERNATIONAL	FR
SOOLANTRA 10 mg/g, crème	SE/H/1428/001	34009 300 241 4 0	GALDERMA INTERNATIONAL	FR
◆◆◆◆◆◆◆◆◆◆ 10 mg/g ◆◆◆◆	SE/H/1428/001	20150192	GALDERMA INTERNATIONAL	BG
Soolantra 10 mg/g crème	SE/H/1428/001	BE 472657	GALDERMA BENELUX B.V.	LU
Soolantra 10 mg/g Creme	SE/H/1428/001	BE 472657	GALDERMA BENELUX B.V.	LU
Soolantra 10 mg/g Creme	SE/H/1428/001	136170	GALDERMA INTERNATIONAL	AT
Soolantra 10 mg/g krem	SE/H/1428/001	22591	GALDERMA POLSKA SP. Z O.O.	PL

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 10 mg/g cremă	SE/H/1428/001	7674/2015/02	GALDERMA INTERNATIONAL	RO
Soolantra 10 mg/g cremă	SE/H/1428/001	7674/2015/03	GALDERMA INTERNATIONAL	RO
Soolantra 10 mg/g cremă	SE/H/1428/001	7674/2015/04	GALDERMA INTERNATIONAL	RO
Soolantra 10 mg/g cremă	SE/H/1428/001	7674/2015/05	GALDERMA INTERNATIONAL	RO
Soolantra 10 mg/g κρέμα	SE/H/1428/001	022320	GALDERMA INTERNATIONAL	CY
Soolantra 10 mg/g κρέμα	SE/H/1428/001	92257/17/30-4-2018	GALDERMA INTERNATIONAL	GR
Soolantra 10 mg/g cream	SE/H/1428/001	PL 10590/0063	GALDERMA (UK) LIMITED	UK
Soolantra 10 mg/g krém	SE/H/1428/001	OGYI-T-22822/01	GALDERMA INTERNATIONAL	HU
Soolantra 10 mg/g crème	SE/H/1428/001	BE 472657	GALDERMA BENELUX B.V.	BE

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 10 mg/g krém	SE/H/1428/001	OGYI-T-22822/02	GALDERMA INTERNATIONAL	HU
Soolantra 10 mg/g krém	SE/H/1428/001	OGYI-T-22822/03	GALDERMA INTERNATIONAL	HU
Soolantra 10 mg/g krém	SE/H/1428/001	OGYI-T-22822/04	GALDERMA INTERNATIONAL	HU
Soolantra 10 mg/g krém	SE/H/1428/001	OGYI-T-22822/05	GALDERMA INTERNATIONAL	HU
Soolantra 10 mg/g crême	SE/H/1428/001	BE 472657	GALDERMA BENELUX B.V.	BE
Soolantra 10 mg/g Creme	SE/H/1428/001	BE 472657	GALDERMA BENELUX B.V.	BE
Soolantra 10 mg/g krem	SE/H/1428/001	14-10067	GALDERMA NORDIC AB	NO
Soolantra 10 mg/g creme	SE/H/1428/001	5645171	LABORATORIOS GALDERMA SA – SUCURSAL EM PORTUGAL	PT
Soolantra 10 mg/g cream	SE/H/1428/001	MA117/01101	GALDERMA INTERNATIONAL	MT

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	54123	GALDERMA NORDIC AB	DK
Soolantra 10 mg/g kräm	SE/H/1428/001	51097	GALDERMA NORDIC AB	SE
Soolantra 10 mg/g krem	SE/H/1428/001	IS/1/15/048/01	GALDERMA NORDIC AB	IS
Soolantra 10 mg/g cream	SE/H/1428/001	PA 590/28/1	GALDERMA (UK) LIMITED	IE
Soolantra 10 mg/g crème	SE/H/1428/001	RVG 115310	GALDERMA BENELUX B.V.	NL
Soolantra 10 mg/g krém	SE/H/1428/001	46/241/15-C	GALDERMA INTERNATIONAL	CZ
Soolantra 10 mg/g emulsiovoide	SE/H/1428/001	32238	GALDERMA NORDIC AB	FI
Soolantra 10 mg/g krém	SE/H/1428/001	32238	GALDERMA NORDIC AB	FI
Soolantra 10 mg/g kremas	SE/H/1428/001	LT/1/15/3726/001	GALDERMA INTERNATIONAL	LT

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 10 mg/g Creme	SE/H/1428/001	92429.00.00	GALDERMA LABORATORIUM GMBH	DE
Soolantra 10 mg/g kremas	SE/H/1428/001	LT/1/15/3726/002	GALDERMA INTERNATIONAL	LT
Soolantra 10 mg/g kremas	SE/H/1428/001	LT/1/15/3726/003	GALDERMA INTERNATIONAL	LT
Soolantra 10 mg/g kremas	SE/H/1428/001	LT/1/15/3726/004	GALDERMA INTERNATIONAL	LT
Soolantra 10 mg/g kremas	SE/H/1428/001	LT/1/15/3726/005	GALDERMA INTERNATIONAL	LT
Soolantra 10 mg/g kreem	SE/H/1428/001	872915	GALDERMA INTERNATIONAL	EE
Soolantra 10 mg/g krém	SE/H/1428/001	46/0218/15-S	GALDERMA INTERNATIONAL	SK
Efacti 10 mg/g crema	SE/H/1428/001	043463013	GALDERMA ITALIA S.P.A.	IT
Efacti 10 mg/g crema	SE/H/1428/001	043463025	GALDERMA ITALIA S.P.A.	IT

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
Efacti 10 mg/g crema	SE/H/1428/001	043463037	GALDERMA ITALIA S.P.A.	IT
Efacti 10 mg/g crema	SE/H/1428/001	043463049	GALDERMA ITALIA S.P.A.	IT
Efacti 10 mg/g crema	SE/H/1428/001	043463052	GALDERMA ITALIA S.P.A.	IT
Soolantra 10 mg/g crema	SE/H/1428/001	7674/2015/01	GALDERMA INTERNATIONAL	RO
SOOLANTRA 10 mg/g, crème	SE/H/1428/001	34009 300 241 0 2	GALDERMA INTERNATIONAL	FR
Soolantra 10 mg/g crema	SE/H/1428/001	79911	LABORATORIOS GALDERMA SA	ES
Soolantra 10 mg/g krēms	SE/H/1428/001	15-0136	GALDERMA INTERNATIONAL	LV
SOOLANTRA 10 mg/g, crème	SE/H/1428/001	34009 300 241 1 9	GALDERMA INTERNATIONAL	FR
SOOLANTRA 10 mg/g, crème	SE/H/1428/001	34009 300 241 2 6	GALDERMA INTERNATIONAL	FR

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 10 mg/g, crème	SE/H/1428/001	34009 300 241 4 0	GALDERMA INTERNATIONAL	FR
◆◆◆◆◆◆◆◆◆◆ 10 mg/g ◆◆◆◆	SE/H/1428/001	20150192	GALDERMA INTERNATIONAL	BG
Soolantra 10 mg/g crème	SE/H/1428/001	BE 472657	GALDERMA BENELUX B.V.	LU
Soolantra 10 mg/g Creme	SE/H/1428/001	BE 472657	GALDERMA BENELUX B.V.	LU
Soolantra 10 mg/g Creme	SE/H/1428/001	136170	GALDERMA INTERNATIONAL	AT
Soolantra 10 mg/g krem	SE/H/1428/001	22591	GALDERMA POLSKA SP. Z O.O.	PL
Soolantra 10 mg/g cremă	SE/H/1428/001	7674/2015/02	GALDERMA INTERNATIONAL	RO
Soolantra 10 mg/g cremă	SE/H/1428/001	7674/2015/03	GALDERMA INTERNATIONAL	RO
Soolantra 10 mg/g cremă	SE/H/1428/001	7674/2015/04	GALDERMA INTERNATIONAL	RO

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 10 mg/g cremă	SE/H/1428/001	7674/2015/05	GALDERMA INTERNATIONAL	RO
Soolantra 10 mg/g κρέμα	SE/H/1428/001	022320	GALDERMA INTERNATIONAL	CY
Soolantra 10 mg/g κρέμα	SE/H/1428/001	92257/17/30-4-2018	GALDERMA INTERNATIONAL	GR