



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

05 September 2019
EMA/496795/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: alitretinoin (oral use)

Procedure no.: PSUSA/00010710/201901

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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
TOCTINO 10 mg Weichkapseln	DK/H/1377/001	1-28037	GLAXOSMITHKLINE PHARMA GMBH.	AT
TOCTINO 30 mg Weichkapseln	DK/H/1377/002	1-28038	GLAXOSMITHKLINE PHARMA GMBH.	AT
Toctino, bløde kapsler	DK/H/1377/001	42008	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	DK
Toctino 30 mg kapselit, pehmeä	DK/H/1377/002	24079	GLAXOSMITHKLINE OY	FI
Toctino 10 mg kapselit, pehmeä	DK/H/1377/001	24078	GLAXOSMITHKLINE OY	FI
Toctino 10 mg Weichkapseln	DK/H/1377/001	71216.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Toctino 30 mg Weichkapseln	DK/H/1377/002	71255.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Toctino 30 mg mjúk hylki	DK/H/1377/002	IS/1/09/077/02	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	IS
Toctino 10 mg mjúk hylki	DK/H/1377/001	IS/1/09/077/01	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	IS
TOCTINO 30 mg capsule molli	DK/H/1377/002	038849030	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	IT
TOCTINO 30 mg capsule molli	DK/H/1377/002	038849042	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	IT
TOCTINO 10 mg capsule molli	DK/H/1377/001	038849016	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	IT
TOCTINO 10 mg capsule molli	DK/H/1377/001	038849028	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	IT
Toctino 10 mg, capsules, zacht	DK/H/1377/001	RVG 100957	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	NL

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
Toctino 30 mg, capsules, zacht	DK/H/1377/002	RVG 100962	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	NL
Toctino 10 mg myke kapsler	DK/H/1377/001	09-6715	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	NO
Toctino 30 mg myke kapsler	DK/H/1377/002	09-6716	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	NO
Toctino 10 mg mäkké kapsuly	DK/H/1377/001	46/0139/10-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	SK
Toctino 30 mg mäkké kapsuly	DK/H/1377/002	46/0140/10-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	SK
Toctino 10 mg capsules, soft	DK/H/1377/001	PL 19494/0252	GLAXOSMITHKLINE UK LIMITED	UK
Toctino 30 mg capsules, soft	DK/H/1377/002	PL 19494/0253	GLAXOSMITHKLINE UK LIMITED	UK
Toctino 10 mg cápsulas blandas	DK/H/1377/001	70.843	STIEFEL FARMA, S.A.	ES
Toctino 30 mg cápsulas blandas	DK/H/1377/002	70.844	STIEFEL FARMA, S.A.	ES
Toctino 10 mg kapslar, mjuka	DK/H/1377/001	24078	GLAXOSMITHKLINE OY	FI
Toctino 30 mg kapslar, mjuka	DK/H/1377/002	24079	GLAXOSMITHKLINE OY	FI
Toctino, bløde kapsler	DK/H/1377/002	42009	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	DK
TOCTINO 30 mg, capsule molle	DK/H/1377/002	NL34848	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	FR
TOCTINO kapsulki miekkie 30 mg	DK/H/1377/002	17606	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	PL
TOCTINO 10 mg, capsule molle	DK/H/1377/001	NL34847	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	FR
TOCTINO kapsułki miękkie 10 mg	DK/H/1377/001	17605	STIEFEL LABORATORIES	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
			LEGACY (IRELAND) LTD	
TOCTINO 30 mg mehke kapsule	DK/H/1377/002	H/10/01534/002	GLAXOSMITHKLINE D.O.O.	SI
TOCTINO 10 mg mehke kapsule	DK/H/1377/001	H/10/01534/001	GLAXOSMITHKLINE D.O.O.	SI
CEHADO 10 mg καψάκια μαλακά	DK/H/1377/001	2884101	GLAXOSMITHKLINE AEBE	GR
CEHADO 30 mg καψάκια μαλακά	DK/H/1377/002	2884102	GLAXOSMITHKLINE AEBE	GR