



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 April 2020
EMA/218763/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: allergen for therapy: Dermatophagoides pteronyssinus / Dermatophagoides farina (oromucosal use, products authorised via mutually recognition procedure and decentralised procedure)

Procedure no.: PSUSA/00010582/201909



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
Aitaro 12 SQ-HDM Lyophilisat zum Einnehmen	DE/H/1950/001	PEI.H.11820.01.1	ALK-ABELLO A/S	DE
ACARIZAX 12 SQ-HDM liofilizado oral	DE/H/1950/001	81213	ALK-ABELLO A/S	ES
ACARIZAX 12 SQ-HDM belsőleges liofilizátum	DE/H/1950/001	OGYI-T-23616/01	ALK-ABELLO A/S	HU
ACARIZAX 12 SQ-HDM belsőleges liofilizátum	DE/H/1950/001	OGYI-T-23616/02	ALK-ABELLO A/S	HU
ACARIZAX 12 SQ-HDM belsőleges liofilizátum	DE/H/1950/001	OGYI-T-23616/03	ALK-ABELLO A/S	HU
Amitend 12 SQ-HDM Lyophilisat zum Einnehmen	DE/H/1951/001	PEI.H.11821.01.1	ALK-ABELLO A/S	DE
ACARIZAX 12 SQ-HDM, lyofilisaat voor oraal gebruik	DE/H/1951/001	RVG 118889	ALK-ABELLO A/S	NL
Acarizax 12 SQ-HDM smeltetablett	DE/H/1947/001	14-10408	ALK-ABELLO A/S	NO
ACARIZAX 12 SQ-HDM Lyophilisat zum Einnehmen	DE/H/1947/001	PEI.H.11754.01.1	ALK-ABELLO A/S	DE
Acarizax, frysetørrede tabletter	DE/H/1947/001	55024	ALK-ABELLO A/S	DK
ACARIZAX 12 SQ-HDM tabletti, kylmäkuivattu	DE/H/1947/001	32830	ALK-ABELLO A/S	FI
ACARIZAX 12 SQ-HDM frystorkad tablett	DE/H/1947/001	52085	ALK-ABELLO A/S	SE
ACARIZAX 12 SQ-HDM perorálny lyofilizát	DE/H/1947/001	59/0472/15-S	ALK-ABELLO A/S	SK
ACARIZAX 12 SQ-HDM, perorální lyofilizát	DE/H/1947/001	59/558/15-C	ALK-ABELLO A/S	CZ

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ACARIZAX 12 SQ-HDM Lyophilisat zum Einnehmen	DE/H/1947/001	236641	ALK-ABELLO A/S	AT
ACARIZAX 12 SQ-HDM, lyophilisat oral	DE/H/1947/001	3400930045336	ALK-ABELLO A/S	FR
ACARIZAX 12 SQ-HDM, lyophilisat oral	DE/H/1947/001	3400930045343	ALK-ABELLO A/S	FR
ACARIZAX 12 SQ-HDM, lyophilisat oral	DE/H/1947/001	3400955016731	ALK-ABELLO A/S	FR
ACARIZAX, 12 SQ-HDM, liofolizat doustny	DE/H/1947/001	22945	ALK-ABELLO A/S	PL
ACCARIZAX 12 SQ-HDM liofilizzato orale	DE/H/1947/001	043755038	ALK-ABELLO A/S	IT
ACCARIZAX 12 SQ-HDM liofilizzato orale	DE/H/1947/001	043755014	ALK-ABELLO A/S	IT
ACCARIZAX 12 SQ-HDM liofilizzato orale	DE/H/1947/001	043755026	ALK-ABELLO A/S	IT