



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 April 2023
EMA/173365/2023
Human Medicines Division

List of nationally authorised medicinal products

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

Procedure No. PSUSA/00010582/202209



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
ACARIZAX 12 SQ-HDM Lyophilisat zum Einnehmen.	DE/H/1947/001	236641	ALK-ABELLO A/S	AT
ACTAIR 100 IR + 300 IR Sublingualtabletten	DE/H/4913/002	140790	STALLERGENES	AT
ACTAIR 100 IR Sublingualtabletten	DE/H/4913/001	140791	STALLERGENES	AT
ACTAIR 300 IR Sublingualtabletten	DE/H/4913/003	140789	STALLERGENES	AT
Acarizax 12 SQ-HDM lyophilisat oral	DE/H/1950/001	BE549822	ALK-ABELLO A/S	BE
Acarizax 12 SQ-HDM, lyophilisaat voor oraal gebruik	DE/H/1950/001	BE549822	ALK-ABELLO A/S	BE
ACARIZAX 12 SQ-HDM, Lyophilisat zum Einnehmen	DE/H/1950/001	BE549822	ALK-ABELLO A/S	BE
ORYLMYTE 100 IR & 300 IR tabletten voor sublinguaal gebruik.	DE/H/4913/002	BE588195	STALLERGENES	BE
ORYLMYTE 100 IR comprimés sublinguaux	DE/H/4913/001	BE588204	STALLERGENES	BE
ORYLMYTE 100 IR et 300 IR comprimés sublinguaux	DE/H/4913/002	BE588195	STALLERGENES	BE
ORYLMYTE 100 IR tabletten voor sublinguaal gebruik	DE/H/4913/001	BE588204	STALLERGENES	BE
ORYLMYTE 300 IR comprimés sublinguaux	DE/H/4913/003	BE588213	STALLERGENES	BE
ORYLMYTE 300 IR tabletten voor sublinguaal gebruik	DE/H/4913/003	BE588213	STALLERGENES	BE
АКТАИР 100 IR и 300 IR сублингвални таблетки	DE/H/4913/002	20210315	STALLERGENES	BG
АКТАИР 100 IR сублингвални таблетки	DE/H/4913/001	20210314	STALLERGENES	BG

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
AKTAIP 300 IR сублингвални таблетки	DE/H/4913/003	20210316	STALLERGENES	BG
ACARIZAX 12 SQ-HDM perorální lyofilizát	DE/H/1947/001	59/558/15-C	ALK-ABELLO A/S	CZ
ACTAIR 100 IR sublingvální tablety	DE/H/4913/001	59/133/20-C	STALLERGENES	CZ
ACTAIR 100 IR sublingvální tablety + ACTAIR 300 IR sublingvální tablety	DE/H/4913/002	59/134/20-C	STALLERGENES	CZ
ACTAIR 300 IR sublingvální tablety	DE/H/4913/003	59/135/20-C	STALLERGENES	CZ
ACARIZAX 12 SQ-HDM Lyophilisat zum Einnehmen.	DE/H/1947/001	PEI.H.11754.01.1	ALK-ABELLO A/S	DE
Aitaro 12 SQ-HDM Lyophilisat zum Einnehmen	DE/H/1950/001	PEI.H.11820.01.1	ALK-ABELLO A/S	DE
AMITEND 12 SQ-HDM Lyophilisat zum Einnehmen.	DE/H/1951/001	PEI.H.11821.01.1	ALK-ABELLO A/S	DE
ORYLMYTE 100 IR & 300 IR Sublingualtabletten	DE/H/4913/002	PEI.H.12040.02.1	STALLERGENES	DE
ORYLMYTE 100 IR Sublingualtabletten	DE/H/4913/001	PEI.H.12040.01.1	STALLERGENES	DE
ORYLMYTE 300 IR Sublingualtabletten	DE/H/4913/003	PEI.H.12040.03.1	STALLERGENES	DE
Acarizax, frysetørrede tabletter	DE/H/1947/001	55024	ALK-ABELLO A/S	DK
Aitmyte, sublinguale resoribletter 100 RI	DE/H/4913/001	64344	STALLERGENES	DK
Aitmyte, sublinguale resoribletter 100+300 RI	DE/H/4913/002	64903	STALLERGENES	DK
Aitmyte, sublinguale resoribletter 300 RI	DE/H/4913/003	64904	STALLERGENES	DK
ACARIZAX 12 SQ-HDM líoofilizado oral.	DE/H/1950/001	81213	ALK-ABELLO A/S	ES

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Actair 100 IR & 300 IR comprimidos sublinguales	DE/H/4913/002	86402	STALLERGENES	ES
Actair 100 IR comprimidos sublinguales	DE/H/4913/001	86403	STALLERGENES	ES
Actair 300 IR comprimidos sublinguales	DE/H/4913/003	86405	STALLERGENES	ES
ACARIZAX 12 SQ-HDM tabletti, kylmäkuivattu	DE/H/1947/001	32830	ALK-ABELLO A/S	FI
ACARIZAX 12 SQ-HDM, lyophilisat oral	DE/H/1947/001	34009 300 453 3 6	ALK-ABELLO A/S	FR
ACARIZAX 12 SQ-HDM, lyophilisat oral	DE/H/1947/001	34009 300 453 4 3	ALK-ABELLO A/S	FR
ACARIZAX 12 SQ-HDM, lyophilisat oral	DE/H/1947/001	34009 550 167 3 1	ALK-ABELLO A/S	FR
ORYLMYTE 100 IR, comprimé sublingual	DE/H/4913/001	34009 302 359 9 7	STALLERGENES	FR
ORYLMYTE 100 IR, comprimé sublingual	DE/H/4913/001	34009 302 360 0 0	STALLERGENES	FR
ORYLMYTE 100 IR, comprimé sublingual ORYLMYTE 300 IR, comprimé sublingual	DE/H/4913/002	34009 302 360 2 4	STALLERGENES	FR
ORYLMYTE 300 IR, comprimé sublingual	DE/H/4913/003	34009 302 360 1 7	STALLERGENES	FR
ORYLMYTE 300 IR, comprimé sublingual	DE/H/4913/003	34009 550 836 8 9	STALLERGENES	FR
ACARIZAX 12 SQ-HDM oralni liofilizat	DE/H/1950/001	HR-H-514558232	ALK-ABELLO A/S	HR
ORYLMYTE 100 IR i 300 IR sublingvalne tablete	DE/H/4913/001-003	HR-H-839244660	STALLERGENES	HR
ORYLMYTE 100 IR sublingvalne tablete	DE/H/4913/001	HR-H-923307797	STALLERGENES	HR
ORYLMYTE 300 IR sublingvalne tablete	DE/H/4913/003	HR-H-696635390	STALLERGENES	HR

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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
ACARIZAX 12 SQ-HDM oral lyophilisate	DE/H/1950/001	PA1255/010/001	ALK-ABELLO A/S	IE
ACTAIR 100 IR & 300IR sublingual tablets	DE/H/4913/002	PA2113/002/002	STALLERGENES	IE
ACTAIR 100 IR sublingual tablets	DE/H/4913/001	PA2113/002/001	STALLERGENES	IE
ACTAIR 300 IR sublingual tablets	DE/H/4913/003	PA2113/002/003	STALLERGENES	IE
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
ORYLMYTE 100 IR & 300 IR compresse sublinguali	DE/H/4913/003	048824041	STALLERGENES	IT
ORYLMYTE 100 IR compresse sublinguali	DE/H/4913/001	048824015	STALLERGENES	IT
ORYLMYTE 100 IR compresse sublinguali	DE/H/4913/001	048824027	STALLERGENES	IT
ORYLMYTE 300 IR compresse sublinguali	DE/H/4913/002	048824054	STALLERGENES	IT
ORYLMYTE 300 IR compresse sublinguali	DE/H/4913/002	048824066	STALLERGENES	IT
Acarizax 12 SQ-HDM lyophilisat oral	DE/H/1950/001	2020020052	ALK-ABELLO A/S	LU
Acarizax 12 SQ-HDM Lyophilisat zum Einnehmen.	DE/H/1950/001	2020020052	ALK-ABELLO A/S	LU
ORYLMYTE 100 IR & 300 IR Sublingualtabletten	DE/H/4913/002	2021080158	STALLERGENES	LU

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ORYLMYTE 100 IR Sublingualtabletten	DE/H/4913/001	2021080157	STALLERGENES	LU
ORYLMYTE 300 IR Sublingualtabletten	DE/H/4913/003	2021080159	STALLERGENES	LU
ACARIZAX 12 SQ-HDM, lyofilisaat voor oraal gebruik	DE/H/1951/001	RVG 118889	ALK-ABELLO A/S	NL
ACTAIR 100 IR en 300 IR, tabletten voor sublinguaal gebruik.	DE/H/4913/002	RVG 126703	STALLERGENES	NL
Actair 100 IR, tabletten voor sublinguaal gebruik.	DE/H/4913/001	RVG 126694	STALLERGENES	NL
Actair 300 IR, tabletten voor sublinguaal gebruik.	DE/H/4913/003	RVG 126704	STALLERGENES	NL
Acarizax 12 SQ-HDM smeltetablett	DE/H/1947/001	14-10408	ALK-ABELLO A/S	NO
Aitmyte 100 RI og 300 RI sublingvaltabletter	DE/H/4913/002	20-13438	STALLERGENES	NO
Aitmyte 100 RI sublingvaltabletter	DE/H/4913/001	20-13437	STALLERGENES	NO
Aitmyte 300 RI sublingvaltabletter	DE/H/4913/003	20-13439	STALLERGENES	NO
ACARIZAX, 12 SQ-HDM, liofolizat doustny	DE/H/1947/001	22945	ALK-ABELLO A/S	PL
ACTAIR, 100 IR i 300 IR, tabletki podjęzykowe	DE/H/4913/002	27087	STALLERGENES	PL
ACTAIR, 100 IR, tabletki podjęzykowe	DE/H/4913/001	27086	STALLERGENES	PL
ACTAIR, 300 IR, tabletki podjęzykowe	DE/H/4913/003	27088	STALLERGENES	PL
ACARIZAX® 12 SQ-HDM liofilizado oral	DE/H/1950/001	5807367	ALK-ABELLO A/S	PT
ACARIZAX® 12 SQ-HDM liofilizado oral	DE/H/1950/001	5807375	ALK-ABELLO A/S	PT
ACTAIR 100 IR comprimidos sublinguais	DE/H/4913/001	5826359	STALLERGENES	PT

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ACTAIR 100 IR comprimidos sublinguais	DE/H/4913/001	5826342	STALLERGENES	PT
ACTAIR 100 IR e 300 IR comprimidos sublinguais	DE/H/4913/002	5826367	STALLERGENES	PT
ACTAIR 300 IR comprimidos sublinguais	DE/H/4913/003	5826375	STALLERGENES	PT
ACTAIR 300 IR comprimidos sublinguais	DE/H/4913/003	5826409	STALLERGENES	PT
ACARIZAX 12 SQ-HDM liofilizat oral	DE/H/1950/001	13325/2020/01	ALK-ABELLO A/S	RO
ACARIZAX 12 SQ-HDM liofilizat oral	DE/H/1950/001	13325/2020/02	ALK-ABELLO A/S	RO
ACARIZAX 12 SQ-HDM liofilizat oral	DE/H/1950/001	13325/2020/03	ALK-ABELLO A/S	RO
ACTAIR 100 IR comprimate sublinguale	DE/H/4913/001	14055/2021/01	STALLERGENES	RO
ACTAIR 100 IR comprimate sublinguale	DE/H/4913/001	14055/2021/02	STALLERGENES	RO
ACTAIR 100 IR și 300 IR comprimate sublinguale	DE/H/4913/002	14056/2021/01	STALLERGENES	RO
ACTAIR 300 IR comprimate sublinguale	DE/H/4913/003	14057/2021/01	STALLERGENES	RO
ACTAIR 300 IR comprimate sublinguale	DE/H/4913/003	14057/2021/02	STALLERGENES	RO
ACARIZAX 12 SQ-HDM frystorkad tablett	DE/H/1947/001	52085	ALK-ABELLO A/S	SE
Aitmyte 100 RI och 300 RI sublinguala resoribletter	DE/H/4913/002	60615	STALLERGENES	SE
Aitmyte 100 RI sublinguala resoribletter	DE/H/4913/001	60614	STALLERGENES	SE
Aitmyte 300 RI sublinguala resoribletter	DE/H/4913/003	60616	STALLERGENES	SE
ACARIZAX 12 SQ-HDM peroralni liofilizat	DE/H/1950/001	H/20/02701/003	ALK-ABELLO A/S	SI
ACARIZAX 12 SQ-HDM peroralni liofilizat	DE/H/1950/001	H/20/02701/001	ALK-ABELLO A/S	SI

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ACARIZAX 12 SQ-HDM peroralni liofilizat	DE/H/1950/001	H/20/02701/002	ALK-ABELLO A/S	SI
Actair 100 IR in 300 IR podjezične tablete	DE/H/4913/002	H/21/02865/003	STALLERGENES	SI
Actair 100 IR podjezične tablete	DE/H/4913/001	H/21/02865/001	STALLERGENES	SI
Actair 100 IR podjezične tablete	DE/H/4913/001	H/21/02865/002	STALLERGENES	SI
Actair 300 IR podjezične tablete	DE/H/4913/003	H/21/02865/004	STALLERGENES	SI
Actair 300 IR podjezične tablete	DE/H/4913/003	H/21/02865/005	STALLERGENES	SI
ACARIZAX 12 SQ-HDM perorálny lyofilizát	DE/H/1947/001	59/0472/15-S	ALK-ABELLO A/S	SK
ACTAIR 100 IR sublingválne tablety	DE/H/4913/001	59/0208/21-S	STALLERGENES	SK
ACTAIR 100 IR sublingválne tablety, ACTAIR 300 IR sublingválne tablety	DE/H/4913/002	59/0209/21-S	STALLERGENES	SK
ACTAIR 300 IR sublingválne tablety	DE/H/4913/003	59/0210/21-S	STALLERGENES	SK
ACTAIR 100 IR & 300 IR sublingual tablets	DE/H/4913/003	PL 04534/0014	STALLERGENES	XI
ACTAIR 100 IR sublingual tablets	DE/H/4913/001	PL 04534/0013	STALLERGENES	XI
ACTAIR 300 IR sublingual tablets	DE/H/4913/002	PL 04534/0015	STALLERGENES	XI