



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 August 2023
EMA/395418/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): allergen for therapy: Dactylis Glomerata L., Phleum Pratense L., Anthoxanthum Odoratum L., Lolium Perenne L., Poa Pratensis L. (sublingual tablet)

Procedure No. PSUSA/00010465/202212



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
ORALAIR 100 IR + 300 IR Sublingualtabletten Einleitungsbehandlung	DE/1930/001	2-00361	STALLERGENES	AT
ORALAIR 300 IR Sublingualtabletten Fortsetzungsbehandlung	DE/H/1930/002	2 - 00362	STALLERGENES	AT
ORALAIR 100 IR & 300 IR Sublingualtabletten	DE/1930/001	BE364515	STALLERGENES	BE
ORALAIR 100 IR & 300 IR tabletten voor sublinguaal gebruik	DE/H/1930/001	BE364515	STALLERGENES	BE
ORALAIR 100 IR & 300 IR, comprimés sublinguaux	DE/H/1930/001	BE364515	STALLERGENES	BE
ORALAIR 300 IR comprimés sublinguaux	DE/H/1930/002	BE364524	STALLERGENES	BE
ORALAIR 300 IR Sublingualtabletten	DE/1930/002	BE364524	STALLERGENES	BE
ORALAIR 300 IR tabletten voor sublinguaal gebruik	DE/H/1930/002	BE364524	STALLERGENES	BE
ОРАЛАИР 100 IR и 300 IR сублингвални таблетки Първоначално лечение	DE/1930/001	20100376	STALLERGENES	BG
ОРАЛАИР 300 IR сублингвални таблетки	DE/1930/002	20100374	STALLERGENES	BG
ORALAIR 100 IR & 300 IR, sublingvální tablety	DE/H/1930/001	59/160/10-C	STALLERGENES	CZ
ORALAIR 300 IR, sublingvální tablety	DE/H/1930/002	59/159/10-C	STALLERGENES	CZ
ORALAIR 100 IR & 300 IR Sublingualtabletten	DE/H/1930/001	PEI.H.03450.01.1	STALLERGENES	DE

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
ORALAIR 300 IR Sublingualtabletten	DE/1930/002	PEI.H.03450.02.1	STALLERGENES	DE
ORALAIR 100 IR & 300 IR, keelealused tabletid	DE/H/1930/001	672810	STALLERGENES	EE
ORALAIR 300 IR, keelealused tabletid	DE/H/1930/002	672910	STALLERGENES	EE
ORALAIR 300 IR comprimidos sublinguales	DE/H/1930/002	71954	STALLERGENES	ES
ORALAIR INICIO 100 IR y 300 IR comprimidos sublinguales	DE/H/1930/001	71953	STALLERGENES	ES
ORALAIR 100 IR & 300 IR, comprimés sublinguaux	DE/H/1930/001	34009 368 951 64	STALLERGENES	FR
ORALAIR 300 IR, comprimés sublinguaux	DE/H/1930/002	34009 368 952 2 5	STALLERGENES	FR
ORALAIR 300 IR, comprimés sublinguaux	DE/H/1930/002	34009 368 953 9 3	STALLERGENES	FR
ORALAIR 100 IR i 300 IR sublingvalne tablete	DE/H/1930/001	HR-H-086623922	STALLERGENES	HR
ORALAIR 300 IR sublingvalne tablete	DE/H/1930/002	HR-H-592791526	STALLERGENES	HR
ORALAIR 100 IR és 300 IR nyelválatti tableta	DE/H/1930/001	OGYI-T-21527/01	STALLERGENES	HU
ORALAIR 300 IR nyelválatti tableta	DE/1930/002	OGYI-T-21527/03	STALLERGENES	HU
ORALAIR 300 IR nyelválatti tableta	DE/H/1930/002	OGYI-T-21527/02	STALLERGENES	HU
ORALAIR 100 IR& 300 IR sublingual tablets	DE/H/1930/001	PA2113/001/001	STALLERGENES	IE
Oralair 300 IR sublingual tablets	DE/H/1930/002	PA2113/001/002	STALLERGENES	IE
ORALAIR 100 IR & 300 IR compresse sublinguali Inizio del trattamento	DE/H/1930/001	039857014	STALLERGENES	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
ORALAIR 300 IR compresse sublinguali Prosecuzione del trattamento	DE/H/1930/002	039857026	STALLERGENES	IT
ORALAIR 300 IR compresse sublinguali Prosecuzione del trattamento	DE/H/1930/002	039857038	STALLERGENES	IT
ORALAIR 100 IR & 300 IR poliežuvinės tabletės	DE/H/1930/001	LT/1/10/2024/001	STALLERGENES	LT
ORALAIR 300 IR poliežuvinės tabletės	DE/1930/002	LT/1/10/2024/003	STALLERGENES	LT
ORALAIR 300 IR poliežuvinės tabletės	DE/1930/002	LT/1/10/2024/002	STALLERGENES	LT
ORALAIR 100 IR & 300 IR, comprimés sublinguaux	DE/H/1930/001	2010050081	STALLERGENES	LU
ORALAIR 300 IR, comprimés sublinguaux	DE/H/1930/002	2010050082	STALLERGENES	LU
ORALAIR 300 IR, comprimés sublinguaux	DE/H/1930/002	2010050082	STALLERGENES	LU
ORALAIR 100 IR & 300 IR tabletes lietošanai zem mēles Ārstēšanas uzsākšanai	DE/H/1930/001	10-0048	STALLERGENES	LV
ORALAIR 300 IR tabletes lietošanai zem mēles Ārstēšanas turpināšanai	DE/H/1930/002	10-0049	STALLERGENES	LV
ORALAIR 100 IR & 300 IR tabletten voor sublinguaal gebruik	DE/H/1930/001	RVG 105376	STALLERGENES	NL
ORALAIR 300 IR tabletten voor sublinguaal gebruik	DE/H/1930/002	RVG 105380	STALLERGENES	NL
Oralair 100 RI & 300 RI sublingvaltabletter	DE/H/1930/001	22-14962	STALLERGENES	NO
Oralair 300 RI sublingvaltabletter	DE/H/1930/002	22-14963	STALLERGENES	NO

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ORALAIR 100 IR& 300 IR, 100 IR / 300 IR, tabletki podjęzykowe	DE/H/1930/001	16729	STALLERGENES	PL
ORALAIR 300 IR, tabletki podjęzykowe	DE/H/1930/002	16730	STALLERGENES	PL
Oralair 100 IR/ 300 IR comprimidos sublinguais Tratamento de iniciação	DE/H/1930/001	5426440	STALLERGENES	PT
Oralair 300 IR comprimidos sublinguais Tratamento de continuação	DE/H/1930/002	5426424	STALLERGENES	PT
Oralair 300 IR comprimidos sublinguais Tratamento de continuação	DE/H/1930/002	5426432	STALLERGENES	PT
ORALAIR 100 IR & 300 IR comprimate sublinguale Tratament de initiere	DE/H/1930/001	5858/2013/01	STALLERGENES	RO
ORALAIR 300 IR comprimate sublinguale Tratament de continuare	DE/H/1930/002	5859/2013/01	STALLERGENES	RO
ORALAIR 300 IR comprimate sublinguale Tratament de continuare	DE/1930/002	5859/2013/02	STALLERGENES	RO
Aitgrys 100 RI och 300 RI sublinguala resoribletter	DE/H/1930/001	63796	STALLERGENES	SE
Aitgrys 300 RI sublinguala resoribletter	DE/H/1930/002	63797	STALLERGENES	SE
ORALAIR 100 IR in 300 IR podjezicne tablete začetno zdravljenje	DE/H/1930/001	H/10/01187/001	STALLERGENES	SI
ORALAIR 300 IR podjezične tablete	DE/H/1930/002	H/10/01187/002	STALLERGENES	SI

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
ORALAIR 300 IR podjezicne tablete nadaljevalno zdravljenje	DE/H/1930/002	H/10/01187/003	STALLERGENES	SI
Oralair 100 IR & 300 IR sublingválne tablety	DE/H/1930/001	59/0853/09-S	STALLERGENES	SK
Oralair 300 IR sublingválne tablety	DE/H/1930/002	59/0854/09-S	STALLERGENES	SK