



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

01 September 2017
EMA/596847/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

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

Procedure no.: PSUSA/00010465/201612



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
Keolium 100 IR/ 300 IR comprimidos sublinguais Tratamento de iniciação	DE/H/1930/001	5426440	STALLERGENES	PT
Keollum 300 IR comprimidos sublinguais Tratamento de continuação	DE/1930/002	5426424	STALLERGENES	PT
Keollum 300 IR comprimidos sublinguais Tratamento de continuação	DE/H/1930/002	5426432	STALLERGENES	PT
ORALAIR 100 IR & 300 IR compresse sublinguali Inizio del trattamento	DE/H/1930/001	039857014	STALLERGENES	IT
ORALAIR 100 IR & 300 IR poliežuvinės tabletės	DE/H/1930/001	LT/1/10/2024/001	STALLERGENES	LT
ORALAIR 100 IR & 300 IR Sublingualtabletten	DE/1930/001/MR	BE364515	STALLERGENES	BE
ORALAIR 100 IR & 300 IR Sublingualtabletten Einleitungsbehandlung	DE/1930/001	PEI.H.03450.01.1	STALLERGENES	DE
Oralair 100 IR & 300 IR sublingvālne tablety Iniciacná liečba	DE/1930/001	59/0853/09-S	STALLERGENES	SK
ORALAIR 100 IR & 300 IR tabletes lietošanai zem mēles Ārstēšanas uzsākšanai	DE/H/1930/001	10-0048	STALLERGENES	LV
ORALAIR 100 IR & 300 IR tabletten voor sublinguaal gebruik Startbehandeling	DE/H/1930/001	RVG 105376	STALLERGENES	NL
ORALAIR 100 IR & 300 IR tabletten voor sublinguaal gebruik Startbehandeling	DE/1930/001	BE364515	STALLERGENES	BE
ORALAIR 100 IR & 300 IR, 100 IR / 300 IR, tabletki podjęzykowe Leczenie wstępne	DE/H/1930/001	16729	STALLERGENES	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
ORALAIR 100 IR & 300 IR, comprimés sublinguaux Traitement d'initiation	DE/H/1930/001	2010050081	STALLERGENES	LU
ORALAIR 100 IR & 300 IR, comprimés sublinguaux Traitement d'initiation	DE/1930/001	BE364515	STALLERGENES	BE
ORALAIR 100 IR & 300 IR, comprimés sublinguaux Traitement d'initiation	DE/1930/001	3400936895164	STALLERGENES	FR
ORALAIR 100 IR & 300 IR, keelealused tabletid Ravi alustamine	DE/1930/001	672810	STALLERGENES	EE
ORALAIR 100 IR + 300 IR Sublingualtabletten Einleitungsbehandlung	DE/1930/001	2-00361	STALLERGENES	AT
ORALAIR 100 IR és 300 IR nyelvvalatti tabletta Kezdo kezelés	DE/H/1930/001	OGYI-T-21527/01	STALLERGENES	HU
ORALAIR 100 IR in 300 IR podjezične tablete začetno zdravljenje	DE/H/1930/001	5363-I-421/14	STALLERGENES	SI
ORALAIR 100 IR&300 IR, sublingválni tablety Úvodní léčba	DE/H/1930/001	59/160/10-C	STALLERGENES	CZ
ORALAIR 100IR & 300IR comprimé sublinguale Traitement de initiation	DE/H/1930/002	5858/2013/01	STALLERGENES	RO
Oralair 100IR & 300IR sublingual tablets Initiation treatment	DE/H/1930/001	PA2113/001/001	STALLERGENES	IE
ORALAIR 300 IR compresse sublinguali Prosecuzione del trattamento	DE/H/1930/002	039857026	STALLERGENES	IT

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ORALAIR 300 IR compresse sublinguali Prosecuzione del trattamento	DE/H/1930/002	039857038	STALLERGENES	IT
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
ORALAIR 300 IR comprimidos sublinguales Tratamiento de continuación	DE/1930/002	71954	STALLERGENES	ES
ORALAIR 300 IR nyelvalatti tabletta Fenntartó kezelés	DE/H/1930/002	OGYI-T-21527/02	STALLERGENES	HU
ORALAIR 300 IR nyelvalatti tabletta Fenntartó kezelés	DE/1930/002	OGYI-T-21527/03	STALLERGENES	HU
ORALAIR 300 IR podjezicne tablete nadaljevalno zdravljenje	DE/H/1930/002	5363-I-422/14	STALLERGENES	SI
ORALAIR 300 IR podjezicne tablete nadaljevalno zdravljenje	DE/H/1930/002	5363-I-423/14	STALLERGENES	SI
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 300 IR sublingual tablets Continuation treatment	DE/H/1930/002	PA2113/001/002	STALLERGENES	IE
ORALAIR 300 IR Sublingualtabletten	DE/1930/002/MR	BE364524	STALLERGENES	BE

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ORALAIR 300 IR Sublingualtabletten Fortsetzungsbehandlung	DE/H/1930/002	2 – 00362	STALLERGENES	AT
ORALAIR 300 IR Sublingualtabletten Fortsetzungsbehandlung	DE/1930/002	PEI.H.03450.02.1	STALLERGENES	DE
Oralair 300 IR sublingválne tablety Pokracovanie liecby	DE/1930/002	59/0854/09-S	STALLERGENES	SK
ORALAIR 300 IR tabletes lietošanai zem mēles Ārstēšanas turpināšanai	DE/H/1930/002	10-0049	STALLERGENES	LV
ORALAIR 300 IR tabletten voor sublinguaal gebruik Vervolgbehandeling	DE/H/1930/002	BE364524	STALLERGENES	BE
ORALAIR 300 IR tabletten voor sublinguaal gebruik Vervolgbehandeling	DE/H/1930/002	RVG 105380	STALLERGENES	NL
ORALAIR 300 IR, comprimés sublinguaux Traitement d'entretien	DE/H/1930/002	BE364524	STALLERGENES	BE
ORALAIR 300 IR, comprimés sublinguaux Traitement d'entretien	DE/H/1930/002	2010050082	STALLERGENES	LU
ORALAIR 300 IR, comprimés sublinguaux Traitement d'entretien	DE/H/1930/002	2010050082	STALLERGENES	LU
ORALAIR 300 IR, comprimés sublinguaux Traitement d'entretien	DE/H/1930/002	34009 368 952 2 5	STALLERGENES	FR
ORALAIR 300 IR, comprimés sublinguaux Traitement d'entretien	DE/1930/002	3400936895393	STALLERGENES	FR
ORALAIR 300 IR, keelealused tabletid Jätkuravi	DE/H/1930/002	672910	STALLERGENES	EE

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ORALAIR 300 IR, sublingvální tablety Udržovací léčba	DE/H/1930/002	59/159/10-C	STALLERGENES	CZ
ORALAIR 300 IR, tabletki podjęzykowe Kontynuacja leczenia	DE/H/1930/002	16730	STALLERGENES	PL
ORALAIR INICIO 100 IR y 300 IR comprimidos sublinguales Tratamiento de inicio	DE/1930/001	71953	STALLERGENES	ES
ОРАЛАИР 100 IR и 300 IR сублингвални таблетки Първоначално лечение	DE/1930/001	20100376	STALLERGENES	BG
ОРАЛАИР 300 IR сублингвални таблетки Продължаващо лечение	DE/1930/002	20100374	STALLERGENES	BG