



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

02 September 2021
EMA/504007/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: allergen for therapy: betula verrucosa (sublingual tablet) -
authorised via decentralised procedure

Procedure no.: PSUSA/00010815/202101

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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
ITULAZAX 12 SQ-Bet Lyophilisat zum Einnehmen.	DE/H/4908/001	238995	ALK-ABELLO A/S	AT
ITULAZAX 12 SQ-Bet lyophilisaat voor oraal gebruik.	DE/H/4908/001	BE543626	ALK-ABELLO A/S	BE
ITULAZAX 12 SQ-Bet lyophilisat oral	DE/H/4908/001	BE543626	ALK-ABELLO A/S	BE
ITULAZAX 12 SQ-Bet perorální lyofilizát	DE/H/4908/001	59/290/18-C	ALK-ABELLO A/S	CZ
ITULAZAX 12 SQ-Bet Lyophilisat zum Einnehmen.	DE/H/4908/001	PEI.H.11987.01.1	ALK-ABELLO A/S	DE
Itulazax, frysetørrede tabletter	DE/H/4908/001	61480	ALK-ABELLO A/S	DK
ITULAZAX 12 SQ-Bet kylmäkuivattu tabletti	DE/H/4908/001	36240	ALK-ABELLO A/S	FI
ITULAZAX 12 SQ-Bet, lyophilisat oral	DE/H/4908/001	34009 301 901 2 8	ALK-ABELLO A/S	FR
ITULAZAX 12 SQ-Bet, lyophilisat oral	DE/H/4908/001	34009 550 687 5 4	ALK-ABELLO A/S	FR

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ITULAZAX 12 SQ-Bet oralni liofilizat	DE/H/4908/001	HR-H-926972641	ALK-ABELLO A/S	HR
ITULAZAX 12 SQ-Bet oral lyophilisate	DE/H/4908/001	PA 1255/007/001	ALK-ABELLO A/S	IE
ITULAZAX 12 SQ-Bet, Lyophilisat zum Einnehmen.	DE/H/4908/001	2019110284	ALK-ABELLO A/S	LU
ITULAZAX 12 SQ-Bet lyophilisat oral	DE/H/4908/001	2019110284	ALK-ABELLO A/S	LU
ITULAZAX 12 SQ-Bet lyofilisaat voor oraal gebruik.	DE/H/4908/001	RVG 123556	ALK-ABELLO A/S	NL
Itulazax 12 SQ-Bet smeltetablett	DE/H/4908/001	18-12375	ALK-ABELLO A/S	NO
ITULAZAX, 12 SQ-Bet, lioofilizat doustny	DE/H/4908/001	25677	ALK-ABELLO A/S	PL
ITULAZAX 12 SQ-Bet lioofilizat oral	DE/H/4908/001	12455/2019/01	ALK-ABELLO A/S	RO
ITULAZAX 12 SQ-Bet lioofilizat oral	DE/H/4908/001	12455/2019/02	ALK-ABELLO A/S	RO

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ITULAZAX 12 SQ-Bet frystorkad tablett	DE/H/4908/001	58118	ALK-ABELLO A/S	SE
ITULAZAX 12 SQ-Bet peroralni liofilizat	DE/H/4908/001	H/19/02647/001	ALK-ABELLO A/S	SI
ITULAZAX 12 SQ-Bet peroralni liofilizat	DE/H/4908/001	H/19/02647/002	ALK-ABELLO A/S	SI
ITULAZAX 12 SQ-Bet perorálny lyofilizát	DE/H/4908/001	59/0340/19-S	ALK-ABELLO A/S	SK