



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

01 September 2022  
EMA/723821/2022  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance(s): **allergen for therapy: betula verrucosa (sublingual use)**

Procedure No. **PSUSA/00010815/202201**



| <b>Product Name (in authorisation country)</b>      | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|-----------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| 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                                              |
| 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 oral                 | DE/H/4908/001                       | 2019110284                           | ALK-ABELLO A/S                            | LU                                              |
| ITULAZAX 12 SQ-Bet, Lyophilisat zum Einnehmen.      | 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,<br>lioofilizat doustny | DE/H/4908/001 | 25677          | ALK-ABELLO A/S | PL |
| ITULAZAX 12 SQ-Bet<br>lioofilizat oral      | DE/H/4908/001 | 12455/2019/01  | ALK-ABELLO A/S | RO |
| ITULAZAX 12 SQ-Bet<br>lioofilizat oral      | DE/H/4908/001 | 12455/2019/02  | ALK-ABELLO A/S | RO |
| ITULAZAX 12 SQ-Bet<br>frystorkad tablett    | DE/H/4908/001 | 58118          | ALK-ABELLO A/S | SE |
| ITULAZAX 12 SQ-Bet<br>peroralni lioofilizat | DE/H/4908/001 | H/19/02647/001 | ALK-ABELLO A/S | SI |
| ITULAZAX 12 SQ-Bet<br>peroralni lioofilizat | DE/H/4908/001 | H/19/02647/002 | ALK-ABELLO A/S | SI |
| ITULAZAX 12 SQ-Bet<br>perorálny lyofilizát  | DE/H/4908/001 | 59/0340/19-S   | ALK-ABELLO A/S | SK |