swissmedic

Public Summary SwissPAR dated 05 January 2024

Letybo® (active substance: botulinum toxin type A (strain CBFC26))

First authorisation in Switzerland: 12 October 2023

Medicinal product (powder for solution for injection) for transient improvement of the appearance of moderate to severe frown lines between the eyebrows in adults (< 75 years)

Information on authorisation

The medicinal product Letybo contains the active substance botulinum toxin type A (of the CBFC26 strain) and is administered as an intramuscular injection.

Letybo is used in persons who, when frowning in the extreme, exhibit moderate to severe vertical lines between the eyebrows ("glabellar lines"). Letybo lessens the severity of these lines for a limited time. It is intended for adults under 75 years of age for whom such facial lines cause serious psychological stress. Reports on the effect of botulinum toxin type A (BoNT/A) on facial wrinkles first appeared in the early 1990s. Studies on facial wrinkles show that BoNT/A lessens the excessive muscle contraction responsible for them, thus smoothing the facial skin and improving the appearance, e.g. in the case of glabellar lines.

In deciding whether to authorise the medicinal product Letybo, Swissmedic took into account the assessment of the German drug regulatory authority and the corresponding product information.

Since the assessment of the clinical data was based on the assessment reports of a foreign authority, the preconditions for a SwissPAR (Swiss Public Assessment Report – a detailed report for professionals) and a resulting Public Summary SwissPAR are not met. Swissmedic refers to the authorisation of the foreign reference authority (DE/H/6379/001).

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Letybo, the Information for healthcare professionals was not yet available. As soon as the medicinal product becomes available in Switzerland, the Information for healthcare professionals will be made available on the following website: www.swissmedicinfo.ch

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.