swissmedic

Summary report on authorisation dated 16 June 2025

Relfydess® (active substance: botulinum toxin type A (strain I01))

First authorisation in Switzerland: 10 March 2025

Solution for injection for the temporary improvement in the appearance of moderate to severe vertical frown lines between the eyebrows (glabellar lines) and eye wrinkles ("crow's feet") in adults (below 65 years)

About the medicinal product

Relfydess contains the active substance botulinum toxin type A (strain I01) and is administered as an intramuscular injection.
Relfydess is used for the temporary improvement in the appearance of moderate to severe vertical frown lines between the eyebrows (glabellar lines) and in the corners of the eyes ("crow's feet"). The treatment is intended for adult patients under 65 years of age for whom such facial lines cause significant psychological stress.
Reports on the effect of botulinum toxin type A (BoNT/A) first appeared in the early 1990s. Studies showed that BoNT/A lessened excessive muscle contraction, thus temporarily improving the appearance of lines.

In deciding whether to authorise Relfydess, Swissmedic took into account the assessment of the Swedish Medical Products Agency and the corresponding medicinal product information texts.

Since the assessment of the clinical data was based on the assessment reports of this foreign authority, the preconditions for a full SwissPAR (Swiss Public Assessment Report – a detailed report for professionals) and a resulting Summary report on authorisation are not met. Swissmedic refers to the authorisation of the foreign reference authority (SE/H/2438/01/DC).

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Relfydess®

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 Summary report on authorisation.

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.