swissmedic

Public Summary SwissPAR dated 28 March 2024

Nuceiva® (active substance: botulinum toxin type A (KCDC strain))

First authorisation in Switzerland: 16 November 2023

Medicinal product (powder for solution for injection) for transient improvement of the appearance of moderate to severe vertical frown lines between the eyebrows in adults (below 65 years)

Information on authorisation

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

Nuceiva is used in persons who, when frowning in the extreme, exhibit moderate to severe vertical lines between the eyebrows ("glabellar lines"). Nuceiva lessens the severity of these lines for a limited time. It is intended for adults 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 glabellar lines.

In deciding whether to authorise the medicinal product Nuceiva, Swissmedic took into account the assessment of the European Medicines Agency (EMA) and the corresponding 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 Public Summary SwissPAR are not met. Swissmedic refers to the authorisation of the foreign reference authority (EMEA/H/C/004587/0000).

www.ema.europa.eu

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Nuceiva, 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.