26 April 2019
EMA/CHMP/184075/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nuceiva

botulinum toxin type A

On 26 April 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nuceiva, intended for temporary improvement of vertical lines between the eyebrows, when the severity of the above facial lines has an important psychological impact on the person. The applicant for this medicinal product is Evolus Pharma Limited.

Nuceiva will be available as a powder for solution for injection (100 U). The active substance of Nuceiva is botulinum toxin type A, which is produced by the bacteria *Clostridium botulinum* and blocks the release of acetylcholine in the neuromuscular synapses and prevents contraction of muscle cells (ATC code: M03AX01).

The benefits with Nuceiva are its ability to temporally reduce the severity of the glabellar lines following local muscular paralysis. The most common side effects are injection site reactions, eyelid ptosis and headache.

The full indication is: “Nuceiva is indicated for the temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar lines), when the severity of the above facial lines has an important psychological impact in adults below 65 years of age.”

It is proposed that Nuceiva be administered only by physicians experienced in the treatment of glabellar lines and the use of required equipment.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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