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Nuceiva (*botulinum toxin type A*)

An overview of Nuceiva and why it is authorised in the EU

What is Nuceiva and what is it used for?

Nuceiva is a medicine used to temporarily improve the appearance of vertical frown lines between the eyebrows. It is used in adults less than 65 years of age who have moderate to severe facial lines and in whom those lines are having a significant psychological impact.

Nuceiva contains the active substance botulinum toxin type A.

How is Nuceiva used?

Nuceiva is given by injection into the muscles in the forehead whose contractions cause the vertical lines between the eyebrows. The medicine is injected in 5 different places above and between the eyebrows. If no side effects are experienced during the initial treatment, the injections can be repeated after at least 3 months.

The medicine can only be obtained with a prescription and must be given by a doctor with expertise in the treatment of vertical lines between the eyebrows and the use of the required equipment. For more information about using Nuceiva, see the package leaflet or contact your doctor or pharmacist.

How does Nuceiva work?

The active substance in Nuceiva, botulinum toxin type A, is produced by the bacterium *Clostridium botulinum*. The toxin reduces the release of acetylcholine, a chemical messenger that causes muscle contraction. When Nuceiva is injected directly into the muscles above and between the eyebrows, it causes the muscles to relax, helping to make the vertical lines less noticeable.

What benefits of Nuceiva have been shown in studies?

Nuceiva has been shown to make the vertical lines between the eyebrows less noticeable in a main study involving 540 adults with moderate or severe vertical lines that affected their mood or caused symptoms of anxiety or depression.

In the study, Nuceiva was compared with another medicine containing botulinum toxin type A and placebo (a dummy treatment). The effectiveness of treatment was measured using a standard 4-point scale, called glabellar line scale (GLS), where 0 = no lines, 1 = mild, 2 =moderate and 3 = severe.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Thirty days after treatment, 87% (205 out of 235) of adults who received Nuceiva had either mild or no vertical lines between the eyebrows, compared with 83% (202 out of 244) of patients who received another medicine containing botulinum toxin type A and 4% (2 out of 48) of patients who were given placebo.

What are the risks associated with Nuceiva?

The most common side effects with Nuceiva (which may affect up to 1 in 10 people) include headache and drooping eyelids. Serious side effects include drooping eyelids, immune responses (when the body's defence system produces antibodies against the botulinum toxin which stop the medicine from working), spread of the toxin to other parts of the body (which may lead to muscle weakness, difficulty breathing or swallowing, and constipation), development or worsening of disorders affecting the muscles and nerves, and hypersensitivity (allergic) reactions. For the full list of side effects of Nuceiva, see the package leaflet.

Nuceiva must not be used in people with diseases affecting the muscles, such as myasthenia gravis or Eaton-Lambert syndrome, and those who have an infection or inflammation at the planned site of injection. For the full list of restrictions, see the package leaflet.

Why is Nuceiva authorised in the EU?

Nuceiva is at least as effective as another medicine containing botulinum toxin type A and more effective than placebo in adults with moderate to severe vertical lines between the eyebrows. The side effects seen with Nuceiva are as expected from this type of medicine and do not raise any major concerns. Further data on the long-term safety of the medicine will be collected post-marketing.

The European Medicines Agency decided that Nuceiva's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Nuceiva?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Nuceiva have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Nuceiva are continuously monitored. Side effects reported with Nuceiva are carefully evaluated and any necessary action taken to protect patients.

Other information about Nuceiva

Nuceiva received a marketing authorisation valid throughout the EU on 27 September 2019.

Further information on Nuceiva can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/nuceiva.

This overview was last updated in 09-2019.