Prescribing information

NUCEIVA®▼ (botulinum toxin type A) 50 Units powder for solution for injection. Before prescribing, please refer to the Summary of Product Characteristics (SmPC).
Presentation: One vial contains 50 Units botulinum toxin type A produced by *Clostridium botulinum*. After reconstitution, each 0.1 ml of the solution contains 4 units. **Indication:** 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 has an important psychological impact in adults < 65 years old. **Administration:** Intramuscular injection. Care should be taken to ensure not to inject into a blood vessel. Should only be administered by healthcare practitioners with appropriate equipment, qualifications and expertise in this treatment. Once reconstituted, Nuceiva should only be used to treat a single patient during a single session. **Posology:** The recommended dose after reconstitution with sodium chloride 9 mg/ml (0.9%) solution for injection is a total of 20 units divided into five injections of 4 units (0.1ml) each: 2 injections in each corrugator supercilli muscle and 1 injection in the procerus muscle. Botulinum toxin units are not interchangeable from one product to another. Doses recommended in units are different from other botulinum toxin preparations. Treatment interval should not be more frequent than every 3 months. In the absence of any undesirable effects secondary to the previous treatment session, a further treatment session with at least a three-month interval between the treatment sessions is possible. Efficacy and safety of repeat injections beyond 12 months has not been evaluated. **Special populations:** Not recommended in patients > 65 years old. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients (contains human albumin). Generalised disorders of muscle activity (e.g. myasthenia gravis, Eaton Lambert Syndrome). Infection or inflammation at the proposed injection sites. **Warnings & precautions:** Injection into vulnerable anatomical structures such as nerves and blood vessels must be avoided. Caution should be exercised when Nuceiva is used in patients with bleeding disorders, if complications have resulted with previous botulinum toxin injections and when the targeted muscle shows weakness or atrophy. Risk of eyelid ptosis following treatment. Procedure-related events: Needle-related pain and/or anxiety have resulted in vasovagal responses, including transient symptomatic hypotension and syncope. Pre-existing neuromuscular disorders: Patients with unrecognised neuromuscular disorders may be at increased risk of clinically significant systemic effects, including severe dysphagia and respiratory compromise from typical doses of botulinum toxin type A. Hypersensitivity reactions: Anaphylactic reaction may occur after injection of botulinum toxin. Epinephrine (adrenaline) or any other anti-anaphylactic measures should therefore be available. Local and distant spread of toxin effect: Adverse reactions possibly related to the spread of toxin distant from the site of administration have been reported with other botulinum toxins. Patients may experience exaggerated muscle weakness. Swallowing and breathing difficulties are serious and can result in death. Use not recommended in patients with a history of dysphagia and aspiration. Pregnancy and lactation: Not recommended during pregnancy or lactation and in individuals of childbearing potential not using contraception. **Undesirable effects:** The most commonly reported are headache, eyelid ptosis, application site bruising, influenza like illness, injection site bruising, injection site pain and injection site swelling. Serious undesirable effects that may occur include eyelid ptosis, an immune response, distant spread of toxin, development or exacerbation of a neuromuscular disorder and hypersensitivity reactions. For full list of side effects, consult SmPC. **Legal category:** POM **List price:** 50 Units powder for solution for injection per vial: £75.50 **MA number:** PLGB 55681/0002 **MA holder:** Evolus Pharma B.V. Apollolaan 151. 1077 AR Amsterdam. NL.
July 2023 | UK-NUC-2300239

Adverse events should be reported.

Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search MHRA Yellow Card in the Google Play or Apple App store. Adverse events should also be reported to Evolus International Ltd at medicalinformation@evolus.com or 08000541302.