FOR UK HEALTHCARE PRACTITIONERS ONLY

MERZ AESTHETICS®

BOCOUTURE®

Reconstitution Guide

Your simple 3-step guide to reconstituting BOCOUTURE®

BOCOUTURE®
(Botulinum toxin type A)

Free from complexing proteins

Prescribing information can be found on the last page

MERZ AESTHETICS®

Composition

50 Unit Vial: Active ingredient
One vial contains 50 units of Botulinum toxin type A (150 kD), free from complexing proteins.[1]
Excipients Human albumin and sucrose.

100 Unit Vial: Active ingredient
One vial contains 100 units of Botulinum toxin type A (150 kD), free from complexing proteins.[2]
Excipients Human albumin and sucrose.

Unit doses for BOCOUTURE® are not interchangeable with those for other preparations of Botulinum toxin type A.

Storage[1,2]

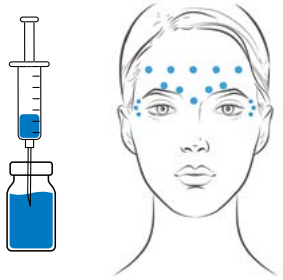
Unopened vial: Do not store above 25°C.

Reconstituted solution: Chemical and physical in-use stability has been demonstrated for 24 hours at 2°C to 8°C. From a microbiological point of view, the product should be used immediately.

Any solution for injection that has been stored for more than 24 hours as well as any unused solution for injection should be discarded.

Administration[1,2]

Reconstituted BOCOUTURE® is intended for intramuscular injection. After reconstitution, BOCOUTURE® should be used immediately and may only be used for one treatment per patient. Reconstituted BOCOUTURE® is injected using a thin sterile needle (e.g. 30–33 gauge / 0.20–0.30 mm diameter / 13 mm length). An injection volume of approximately 0.04 to 0.1 mL per injection site is recommended.



See the SmPC for further information on reconstitution before administration and disposal of the vials.

The intervals between treatments should not be shorter than 3 months. If the treatment fails, or the effect lessens with repeated injections, alternative treatment methods should be used.

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Reconstitution[1,2]

BOCOUTURE® is reconstituted prior to use with sodium chloride 9 mg/mL (0.9%) solution for injection. Reconstitution and dilution should be performed in accordance with good clinical practice guidelines, particularly with respect to asepsis.

It is good practice to reconstitute the vial contents and prepare the syringe over plastic-lined paper towels to catch any spillage. An appropriate amount of sodium chloride solution is drawn up into a syringe.

BOCOUTURE® must not be used if the reconstituted solution has a cloudy appearance or contains floccular or particulate matter.

Practical Considerations for Optimal Reconstitution[3]

- Please note these practical considerations are recommendations based on a study demonstrating the impact of poor mixing technique.
- BOCOUTURE® reconstitution may differ from that of other Botulinum toxin type A products.
- BOCOUTURE® can be found distributed throughout the vial rather than solely at the bottom of the vial, so failure to invert the vial of BOCOUTURE® following the addition of saline may result in reconstitution of less than 100% of the available neuromodulator, possibly resulting in diminished efficacy upon injection.
- The study demonstrated that improper reconstitution of BOCOUTURE®, or swirling without inversion of the vial following saline injection, can result in a significant loss of units of the neurotoxin in a clinical setting.

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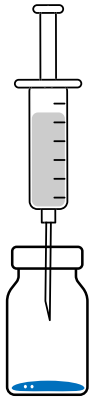
RECONSTITUTION INSTRUCTIONS[1,2]



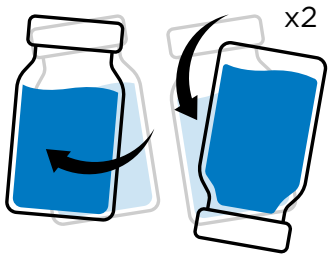
Draw 1.25 mL of sodium chloride 9 mg/mL (0.9%) solution for injection into the syringe, using a needle and suitable syringe.

For 50 units, draw 1.25 mL of sodium chloride solution into the syringe.[1]

For 100 units, draw 2.5 mL of sodium chloride solution into the syringe.[2]

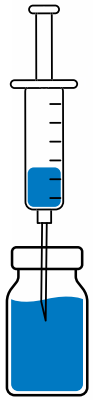
After vertical insertion of the needle through the rubber stopper, the solvent is injected gently into the vial in order to avoid foam formation. A 20–27 gauge short bevel needle is recommended for reconstitution.

The vial must be discarded if the vacuum does not pull the solvent into the vial.



Remove the syringe from the vial and mix BOCOUTURE® with the solvent by carefully swirling and inverting/ flipping the vial.

DO NOT shake vigorously.



Reconstituted BOCOUTURE® is a clear, colourless solution.

If needed, the needle used for reconstitution should remain in the vial and the required amount of solution should be drawn up with a new sterile syringe suitable for injection.

Further Information

For further information on BOCOUTURE®, including the disposal of the vials please see the Summary of Product Characteristics (SmPC) at:

- 50 units: https://www.medicines.org.uk/emc/product/600/smpc
- 100 units: https://www.medicines.org.uk/emc/product/7418/smpc

For any queries, please contact the medical information team at medical.information@merz.com

Prescribing information can be found on the reverse

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BOCOUTURE® (Botulinum toxin type A) | Free from complexing proteins

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Bocouture® (Botulinum toxin type A) Prescribing Information

Bocouture® (botulinum toxin type A (150 kD), free from complexing proteins) 50/100 unit vials. Prescribing information: M-BOC-UK-0432.
Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** 50/100 units of Clostridium Botulinum Neurotoxin type A, free from complexing proteins as a powder for solution for injection. **Indications:** Temporary improvement in the appearance of moderate to severe upper facial lines (glabellar frown lines, crow's feet lines, horizontal forehead lines) in adults ≥18 and <65 years when the severity of these lines has an important psychological impact for the patient. **Dosage and administration:** For intramuscular use only. Unit doses recommended for Bocouture are not interchangeable with those for other preparations of botulinum toxin. BOCOUTURE should only be administered by an appropriately qualified healthcare practitioner with expertise in the treatment of the relevant indication and the use of the required equipment, in accordance with national guidelines . The intervals between treatments should not be shorter than 3 months. Reconstitute with 0.9% sodium chloride. ***Glabellar Frown Lines:*** Total recommended standard dose is 20 units. 4 units into 5 injection sites (2 injections in each corrugator muscle and 1 injection in the procerus muscle). May be increased to up to 30 units. Injections near the levator palpebrae superioris and into the cranial portion of the orbicularis oculi should be avoided. ***Crow's Feet lines:*** Total recommended standard dosing is 12 units per side (overall total dose: 24 units); 4 units injected bilaterally into each of the 3 injection sites. Injections too close to the Zygomaticus major muscle should be avoided to prevent lip ptosis. ***Horizontal Forehead Lines:*** The recommended total dose range is 10 to 20 units; a total injection volume of 10 units to 20 units is injected into the frontalis muscle in five horizontally aligned injection sites at least 2 cm above the orbital rim. An injection volume of 2 units, 3 units or 4 units is applied per injection point, respectively. **Contraindications**: Hypersensitivity to the active substance or to any of the excipients. Generalised disorders of muscle activity (e.g. myasthenia gravis, Lambert-Eaton syndrome). Infection or inflammation at the proposed injection site. **Special warnings and precautions:** It should be taken into consideration that horizontal forehead lines may not only be dynamic, but may also result from the loss of dermal elasticity (e.g. associated with ageing or photo damage). In this case, patients may not respond to botulinum toxin products. Should not be injected into a blood vessel. Not recommended for patients with a history of dysphagia and aspiration. Caution in patients with botulinum toxin hypersensitivity, amyotrophic lateral sclerosis, peripheral neuromuscular dysfunction, or in targeted muscles displaying pronounced weakness or atrophy. Bocouture should be used with caution in patients receiving therapy that could have an anticoagulant effect, or if bleeding disorders of any type occur. Too frequent or too high dosing of botulinum toxin type A may increase the risk of antibodies forming. Should not be used during pregnancy unless clearly necessary. Should not be used during breastfeeding. **Interactions:** Concomitant use with aminoglycosides or spectinomycin requires special care. Peripheral muscle relaxants should be used with caution. 4-aminoquinolines may reduce the effect. **Undesirable effects:** Usually, undesirable effects are observed within the first week after treatment and are temporary in nature. Undesirable effects independent of indication include; application related undesirable effects (localised pain, inflammation, swelling), class related undesirable effects (localised muscle weakness, blepharoptosis), and toxin spread (very rare - exaggerated muscle weakness, dysphagia, aspiration pneumonia). Hypersensitivity reactions have been reported with botulinum toxin products. ***Glabellar Frown Lines:*** Common: headache, muscle disorders (elevation of eyebrow). ***Crow's Feet Lines:*** Common: eyelid oedema, dry eye, injection site haematoma. ***Upper Facial Lines:*** Very common: headache. Common: hypoaesthesia, injection site haematoma, application site pain, application site erythema, discomfort (heavy feeling of frontal area), eyelid ptosis, dry eye, facial asymmetry, nausea. For a full list of adverse reactions, please consult the SmPC. **Overdose:** May result in pronounced neuromuscular paralysis distant from the injection site. Symptoms are not immediately apparent post-injection. **Legal Category:** POM. **List Price:** 50 U/vial £72.00, 50 U twin pack £144.00, 100 U/vial £229.90, 100 U twin pack £459.80. **Product Licence Number:** PL 29978/0002, PL 29978/0005 **Marketing Authorisation Holder:** Merz Pharmaceuticals GmbH, Eckenheimer Landstraße 100,60318 Frankfurt/Main, Germany. **Date of Preparation:August 2021**. **Further information available from:**. Ground Floor Suite B, Breakspear Park, Breakspear Way, Hemel Hempstead, Hertfordshire, HP2 4TZ Tel: **+44 (0) 333 200 4143**

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Merz Pharma UK Ltd by email at UKdrugsafety@merz.com or on +44 (0) 333 200 4143.

1. BOCOUTURE® (incobotulinumtoxinA) 50 units powder for solution for injection. Summary of Product Characteristics. Merz Pharmaceuticals GmbH.
2. BOCOUTURE® (incobotulinumtoxinA) 100 units powder for solution for injection. Summary of Product Characteristics. Merz Pharmaceuticals GmbH.
3. Carey, W.D., Incorrect reconstitution of incobotulinumtoxinA leads to loss of neurotoxin. J Drugs Dermatol. 2014;13(6):735–738.

M-BOC-UK-0438 Date of Preparation December 2021

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BOCOUTURE® (Botulinum toxin type A) | Free from complexing proteins