BOCOUTURE SAFETY INFORMATION

BOCOUTURE® Important Safety Information
BOCOUTURE®, 50 or 100 units, powder for solution for injection. Active substance: Botulinum toxin type A (150 kD), purified from Clostridium Botulinum cultures (Hall strain), free from complexing proteins. Prescription-only medicine! Qualitative and quantitative composition: One vial contains: 50 or 100 units of Botulinum toxin type A (150 kD), free from complexing proteins, human albumin, sucrose. Due to the differences in the potency assay, unit doses are not interchangeable with those for other Botulinum toxin type A preparations. Therapeutic indications: For temporary improvement in the appearance of upper facial lines in adults below 65 years when the severity of these lines has an important psychological impact for the patient:

- *moderate to severe vertical lines between the eyebrows seen at maximum frown*
- *(glabellar frown lines) and/or*
- *moderate to severe lateral periorbital lines seen at maximum smile (crow's feet lines) and/or*
- *moderate to severe horizontal forehead lines seen at maximum contraction.*

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. Should not be used during pregnancy unless clearly necessary and not be used during breast-feeding. Undesirable effects: Undesirable effects usually occur within the first week after injection and are temporary in nature. They may be related to the active substance, the injection procedure, or both. Application-related: Localised pain, inflammation, paraesthesia, hypoaesthesia, tenderness, swelling, oedema, erythema, itching, localised infection, haematoma, bleeding and/or bruising may be associated with the injection. Needle-related pain and/or anxiety may result in vasovagal responses, including transient symptomatic hypotension, nausea, tinnitus, and syncope. Undesirable effects of the substance class Botulinum toxin type A: Localised muscle weakness, blepharoptosis (possibly caused by the injection technique) are an expression of the pharmacological effect. Toxin spread: When treating other indications with Botulinum toxins, undesirable effects related to spread of toxin distant from the site of administration producing symptoms consistent with Botulinum toxin type A effects have been reported very rarely (excessive muscle weakness, dysphagia, and aspiration pneumonia with a fatal outcome in some cases). These cannot be completely ruled out with the use of BOCOUTURE®.

Hypersensitivity reactions: Rare reports of serious and/or immediate hypersensitivity reactions including anaphylaxis, serum sickness, urticaria, soft tissue oedema, and dyspnoea, some of these reactions either following the administration of conventional Botulinum toxin type A complex alone or in combination with other agents known to cause similar reactions. The following undesirable effects were reported from clinical experience with BOCOUTURE®: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100). Vertical lines between the eyebrows seen at maximum frown (Glabellar Frown Lines): Common: Headache, Mephisto sign (lateral elevation of eyebrows); Uncommon: Bronchitis, nasopharyngitis, influenza-like illness, insomnia, eyelid oedema, eyelid ptosis, blurred vision, pruritus, skin nodule, brow ptosis, muscle twitching, muscle spasm, facial asymmetry (brow asymmetry), injection site haematoma, injection site pain, (local) tenderness, fatigue, discomfort (heavy feeling of eyelid/ eyebrow), haematoma. Lateral periorbital lines seen at maximum smile (Crow's Feet Lines): Common: Eyelid oedema, dry eye, injection site haematoma. Upper Facial Lines: Very common: Headache; Common: Hypoaesthesia, injection site haematoma, injection site pain, injection site erythema, discomfort (heavy feeling of the frontal area), eyelid ptosis, dry eye, brow ptosis, facial asymmetry, Mephisto sign (lateral elevation of eyebrows), nausea. Post-marketing experience: Frequency not known: Hypersensitivity reactions like swelling, oedema (also distant from the injection site), erythema, pruritus, rash (localised and generalised), breathlessness, muscle atrophy, flu-like symptoms.

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Further information is provided in the Summary of Product Characteristics and the Package Leaflet.
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