XEOMIN®, 50, 100 or 200 units, powder for solution for injection. **Active substance:** Clostridium botulinum neurotoxin 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, 100 or 200 units of Clostridium botulinum neurotoxin type A (150 kD), free from complexing proteins, human albumin, sucrose. Due to the differences in the potency assays, unit doses are not interchangeable with those for other Botulinum toxin type A preparations.
Therapeutic indications: For the symptomatic treatment in adults of: blepharospasm, and hemifacial spasm, cervical dystonia of a predominantly rotational form (spasmodic torticollis), spasticity of the upper limb, and chronic sialorrhea due to neurological disorders.
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. Do not use during pregnancy unless clearly necessary. Do not use during breast-feeding.
Undesirable effects: Undesirable effects usually occur within the first week following 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. Needle related pain and/or anxiety may result in vasovagal responses, including transient symptomatic hypotension, nausea, tinnitus and syncope. Localised muscle weakness is one expected pharmacological effect of Botulinum toxin type A. Toxin spread: Undesirable effects related to spread of toxin distant from the site of administration have been reported very rarely to produce symptoms consistent with Botulinum toxin type A effects (excessive muscle weakness, dysphagia, and aspiration pneumonia with a fatal outcome in some cases). Hypersensitivity reactions: Rare reports of serious and/or immediate hypersensitivity reactions including anaphylaxis, serum sickness, urticaria, soft tissue oedema, and dyspnoea, sometimes either following the administration of conventional Botulinum toxin type A complex preparations alone or in combination with other active substances known to cause similar reactions.
The following undesirable effects were observed with the clinical use of XEOMIN®: *Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100).*
Blepharospasm: *Very common:* Eyelid ptosis; *Common:* Dry eyes, vision blurred, visual impairment, dry mouth, injection site pain; *Uncommon:* Headache, facial paresis, diplopia, lacrimation increased, dysphagia, rash, muscular weakness, fatigue.
Hemifacial spasm: Similar adverse reactions as for blepharospasm.
Spasmodic torticollis: *Very common*: Dysphagia: dysphagia of varying degrees of severity may cause aspiration which may require medical intervention. Duration: 2-3 weeks post-injection, in one case up to 5 months; *Common:* Upper respiratory tract infection, headache, presyncope, dizziness, dry mouth, nausea, hyperhidrosis, neck pain, muscular weakness, myalgia, muscle spasms, musculoskeletal stiffness, injection site pain, asthenia; *Uncommon:* Speech disorder, dysphonia, dyspnoea, rash.
Spasticity of the upper limb: *Common:* Dry mouth; *Uncommon:* Headache, hypoaesthesia, dysphagia, nausea, muscular weakness, pain in extremity, myalgia, asthenia; *Frequency not known:* Injection site pain.
Chronic sialorrhea: *Common:* Paraesthesia, dry mouth, dysphagia; *Uncommon:* Speech disorder, altered (thickened) saliva, dysgeusia. Cases of persistent dry mouth (> 110 days) of severe intensity have been reported with possible complications as gingivitis, dysphagia and caries.
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.

PLEASE CHECK YOUR LOCAL APPROVAL STATUS

<Phone: +49-69/1503-1> is optional information