Xeomin HCP abridged datasheet

XEOMIN® is a Prescription Medicine. Please review full Product Information before prescribing, available from New Zealand Medical & Scientific Ltd (NZMS) on 09 259 4062.

Xeomin® (Incobotulinumtoxin A, purified Botulinum toxin type A, free from complexing proteins, powder for solution for injection). 50, 100 LD50 Units. **Indications**: In adults, for the treatment of cervical dystonia; blepharospasm; post-stroke spasticity of the upper limb and upper facial lines including forehead, periorbital (crow's feet) and glabellar lines in adults. **Contraindications:** Hypersensitivity to ingredients; generalised disorders of muscle activity (e.g. myasthenia gravis, Lambert-Eaton Syndrome); Infection or inflammation at the proposed injection sites. **Precautions:** bleeding disorders; local and distant spread of toxin effect; pre-existing neuromuscular disorders; hypersensitivity reactions, antibody formation; lack of interchangeability between botulinum toxin products; mild to severe dysphagia, aspiration and dyspnoea; muscle weakness (neck); swallowing, speech or respiratory disorders; avoid injection through pen marks, into blood vessels, near levator palpebrae superioris, inferior oblique and medial injections into the lower lid; ptosis; diplopia; reduced blinking; contains albumin (human); pregnancy (Cat B3); lactation; children (not recommended); driving/using machines; others, see full PI. **Interactions with other medicines**: Aminoglycoside antibiotics; anticoagulants or those with similar effect; other agents interfering with neuromuscular transmission, e.g., tubocurarine-type muscle relaxants. **Adverse effects:** *Cervical Dystonia*: neck pain, muscular weakness, musculoskeletal pain and stiffness, dysphagia, nausea, headache, injection site pain, *Blepharospasm*: dry eyes, eyelid ptosis, vision blurred, dry mouth, *Poststroke spasticity*: muscle weakness *Upper facial lines*: headache, risk of eyelid, brow or lip ptosis; others, see full PI. **Dosage and Administration**: For intramuscular injection, single use in one patient only. Unit doses recommended for Xeomin are not interchangeable with those for other preparations of botulinum toxin. Reconstitute with sodium chloride 9 mg/mL (0.9%) solution for injection (see full PI for dilutions). The optimum dose and number of injection sites in the treated muscle(s) should be individualised for each patient and determined by the treating doctor. *Cervical dystonia*: 0.1 to 0.5 mL/site; max 50 U/site; max 300 U/treatment session. Treatment intervals should be determined based on the actual clinical need of the individual patient and generally no more frequent than every 6 weeks. *Blepharospasm*: 0.05-0.1 mL/ site; max 35 U/eye for pre-treated patients, if the previous dose of botulinum toxin is not known; max 25 U/eye for treatment naïve patients; max 100 U per treatment session. Treatment intervals should be determined based on the actual clinical need of the individual patient and generally no more frequent than every 6 weeks. *Post-stroke spasticity*: max 400 U/treatment session; treatment intervals should be determined based on the actual clinical need of the individual patient and generally no more frequent than every 12 weeks. *Upper facial lines*: Glabellar -0.1 mL/site; max 30 U/treatment session; Periorbital – 0.1ml per site max 12 U per side; Forehead – total dose 10 to 20 U ; treatment intervals should be determined based on the actual clinical need of the individual patient and generally no more frequent than every 3 months; see full PI. Medsafe-approved 18 December 2014. XEOMIN is a registered trademark of Merz Pharma GmbH & Co. KGaA. Copyright ©2014. Prepared 18 February 2015. Xeomin is an unfunded medicine. For more information please contact the New Zealand Distributor: New Zealand Medical and Scientific Ltd, 2a Fisher Crescent, Mt Wellington, Auckland, Phone 09 259 4062. TAPS NA9800.