**Succinct Statement BOTOX®** (Toxinum botulinicum A ) 50 and 100 Allergan-Units

**I:** Neurology: Symptomatic management of blepharospasm, hemifacial spasm and associated focal dystonias, for correction of strabismus in patients older than 12 years. Cervical dystonia (spasmodic torticollis) in adults, symptomatic treatment of focal spasticity of the upper and lower limbs in adults, adolescents and children from 2 years of age and older. Prophylaxis of headache in adult patients with chronic migraine. Skin: Primary hyperhidrosis of the axillae in adults. Bladder: Overactive bladder with symptoms of urinary incontinence, urgency and frequency in adult patients who have an inadequate response to, or are intolerant of, anticholinergic medication. Urinary incontinence due to neurogenic detrusor overactivity associated with a neurologic condition (such as spinal cord injury, multiple sclerosis) in adults. Neurogenic detrusor overactivity associated with a neurological disease (such as spina bifida, spinal cord lesion) in paediatric patients 5 years of age and older whose bladder is reliably emptied by regular disposable catheterization and who have an inadequate response to or are intolerant of anticholinergic medicinal products. **D**: Botulinum toxin units are not inter-changeable from one product to another product. Only be given by physicians with appropriate qualifications, expertise and equipment (e.g. EMG). Dosage depending on indication and individual treatment, optimum dose levels should be determined by titration. **CI**: Known hypersensitivity to the active substance or to any of the excipients. Infection at the proposed injection site(s). Injections into the detrusor: urinary tract infection, acute urinary retention without catheter. **W:** Do not exceed recommended dosages. Consideration should be given to the risk-benefit implications for the individual patient before treatment (history in neurological disorders, dysphagia and aspiration, epilepsia). Prior surgical procedures, injection into vulnerable anatomic structures, presence of inflammation at the proposed injection site, weakness/atrophy in the target muscle; swallowing, speech or respiratory disorders that require an immediate medical care, presence of contra measures in case of anaphylactic reactions; possible reduction of effectiveness by formation of neutralizing antibodies. Caution in patients with peripheral motor neuropathic diseases and defective neuromuscular transmission (e.g. myasthenia gravis or Lambert-Eaton Syndrome). Caution is warranted when injecting in proximity to the lung (particularly the apices). Immediate use of diluted solution in the syringe (e.g. urinary incontinence). **IA:** aminoglycoside antibiotics, spectinomycin or other medicinal products that interfere with neuromuscular transmission (e.g. muscle relaxants), other botulinum toxins. Do not mix with other medicinal products. Not recommended in women of childbearing potential not using contraception, during pregnancy and breastfeeding. **AE:** Very common: eyelid ptosis, eye movement disorder, dysphagia, muscular weakness, pain, urinary tract infection, dysuria, bacteriuria, urinary retention, residual urine volume, injection site pain. **P:** 2 x 1 vials with BOTOX® 50 Allergan Units. 1 and 2 x 1 vials with BOTOX® 100 Allergan Units. List A, with limitatio. **M:** AbbVie AG, Alte Steinhauserstrasse 14, 6330 Cham, tel. (+41) 41 399 15 00. For detailed medicinal product's characteristics see: www.swissmedicinfo.ch (V4).

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