EXTENSIVE EXPERIENCE. A LEGACY YOU CAN TRUST.

> 3,800 studies have been published involving **> 28,000** BOTOX®-treated patients[1]*

> 1 million patients globally are treated with BOTOX® each year[1]

Compared to other botulinum toxin therapies, BOTOX®[1,2]:

- Has the most therapeutic indications in Canada (10)
- Offers the most extensive coverage across indications throughout Canada
- Has a unique molecular structure based on differences in manufacturing processes

The BOTOX® safety profile in post-stroke spasticity has been studied in[2]:

- 399 patients with upper limb spasticity included in double-blind and open-label clinical trials
- 538 patients with lower-limb spasticity included in 7 double-blind, placebo-controlled clinical trials

PrBOTOX® (onabotulinumtoxinA) is indicated[2]:

- In the management of focal spasticity, including the treatment of upper limb spasticity associated with stroke in adults
- For the symptomatic treatment of lower limb spasticity associated with stroke in adults

The term “Allergan unit” upon which dosing is based, is a specific measurement of toxin activity that is unique to Allergan’s formulation of botulinum toxin type A. Therefore, the “Allergan units” used to describe BOTOX® activity are different from those used to describe that of other botulinum toxin preparations and units representing BOTOX® activity are not interchangeable with other products[2]

BOTOX®: Trusted by physicians and patients for over 30 years*

*Across all indications.

Allergan
an AbbVie company

BOTOX®
onabotulinumtoxinA

Clinical use:

Studies specifically designed to determine the dose in elderly patients have not been performed. Dosages for the elderly are as for other adults. Initial dosing should begin at the lowest recommended dose for the specific indication.

The safety and effectiveness of BOTOX® in the management of focal spasticity, including the treatment of upper and lower limb spasticity associated with stroke has not been investigated in children and adolescents under 18 years of age.

Contraindications:

- Patients who are hypersensitive to any botulinum toxin type A or to any ingredient in the formulation or component of the container
- The presence of infection at the proposed injection site(s)

Most serious warnings and precautions:

Not interchangeable: The term "Allergan unit" upon which dosing is based is a specific measurement of toxin activity that is unique to Allergan's formulation of botulinum toxin A. Therefore, the "Allergan units" used to describe BOTOX® activity are different from those used to describe that of other botulinum toxin preparations and the units representing BOTOX® activity are not interchangeable with other products.

Appropriate qualifications and experience: BOTOX® should only be given by physicians with the appropriate qualifications and experience in the treatment and the use of required equipment.

Follow the recommended dosage and frequency of administration for BOTOX®.

Distant spread of toxin effect: The effects of BOTOX® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life-threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can occur in adults, particularly in those patients who have underlying conditions that would predispose them to these symptoms.

Other warnings and precautions:

- Serious adverse events including fatal outcomes have been reported in patients who had received BOTOX® injected directly into salivary glands, the oro-lingual-pharyngeal region, esophagus and stomach; some patients had pre-existing dysphagia or significant debility
- Pneumothorax associated with injection procedure has been reported following administration near the thorax; caution is warranted when injecting in proximity to the lung, particularly the apices
- Caution should be used when BOTOX® is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle
- Muscle weakness remote to the site of injection and other serious adverse effects (e.g. dysphagia, aspiration pneumonia) have been rarely reported in both pediatric and adult patients, in some cases associated with a fatal outcome
- Patients with a history of underlying neurological disorders, dysphagia and/or aspiration should be treated with extreme caution. The botulinum toxin product should be used under specialist supervision in these patients and only if the benefit is considered to outweigh the risk
- Patients or caregivers should be advised to seek immediate medical care if swallowing, speech or respiratory disorders arise
- Cardiovascular events: There have been reports following administration of botulinum toxin of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. The exact relationship with BOTOX® is unknown
- Immune: Formation of neutralizing antibodies to botulinum toxin A may reduce the effectiveness of BOTOX® treatment by inactivating the biological activity of the toxin
- Anaphylactic reactions: As with all biologic products, an anaphylactic reaction may occur, necessary precautions should be taken and epinephrine should be available
- Neurologic: Extreme caution should be exercised with administering BOTOX® to individuals with peripheral motor neuropathic disorders or neuromuscular junction disorders. These patients may be at increased risk of clinically significant systemic effects including severe dysphagia and respiratory compromise from typical doses of BOTOX®, in some cases requiring placement of a gastric feeding tube. When exposed to very high doses, patients with neurologic disorders (e.g., pediatric cerebral palsy or adult spasticity) may also be at increased risk of clinically significant systemic effects
- New onset or recurrent seizures have been reported, typically in patients who are predisposed to experiencing these events
- Skin: As is expected for any injection procedure, localized pain, inflammation, paresthesia, hypoaesthesia, tenderness, swelling/edema, erythema, localized infection, bleeding and/or bruising have been associated with the injection
- Special populations: BOTOX® should not be used during pregnancy unless clearly necessary. Caution should be exercised when BOTOX® is administered to a nursing woman

For more information:

Please consult the Product Monograph at: https://pdf.hres.ca/dpd_pm/00047832.PDF for important information relating to adverse reactions, interactions and dosing information which has not been discussed in this piece.

The Product Monograph is also available by calling: 1-800-668-6424.

REFERENCES: 1. Data on file. Allergan. **2.** BOTOX® Product Monograph, Allergan Inc. October 16, 2018.