



## BOTOX Cosmetic® Fact Sheet

- BOTOX Cosmetic® is a simple, minimally invasive, physician-administered, non-surgical, cosmetic injectable treatment that temporarily reduces muscle activity and softens the look of fine lines and wrinkles for up to four months.
- BOTOX® is a purified protein derived from the bacterium clostridium Botulinum and decreases muscle activity by blocking the overactive nerve impulses that trigger excessive muscle contractions or glandular activities. Once the signal is blocked, the contractions stop and the muscle relaxes.
- In 2001, Health Canada approved BOTOX Cosmetic®, for the treatment of glabellar lines, the vertical “frown lines” between the eyebrows. Since then BOTOX Cosmetic® has received approval for the treatment of upper facial rhytides or “forehead wrinkles” and lateral canthus or “crow’s-feet”.
- BOTOX Cosmetic® is the same medicine that is used to treat patients with neurological conditions under the name BOTOX®. It is, however, generally administered in smaller doses for cosmetic use. The approved doses of BOTOX® for medical uses are generally greater than the approved doses for cosmetic procedures.
  - In 1990, BOTOX® was approved by Health Canada for use in the treatment of blepharospasm (uncontrolled blinking) and strabismus (crossed eyes). In the ensuing 19 years, BOTOX® has received approvals for many additional therapeutic indications including VII facial nerve disorders, cervical dystonia, or the involuntary head rotation caused by muscle spasm (1996), cerebral palsy (1999), hyperhidrosis (2001) and focal spasticity (2001).

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- According to the American Society of Plastic Surgeons (ASPS), over five million BOTOX Cosmetic treatments were administered in 2008 alone.
- Ninety-seven percent of patients were definitely satisfied with BOTOX Cosmetic® treatments, according to a survey of approximately 1,000 patients conducted by the research arm of ASAPS.
- Nearly 29 million treatment sessions have been performed with BOTOX® and BOTOX Cosmetic® in the United States alone over the last 20 years.
- Since its first Canadian approval more than 20 years ago, reports of serious adverse events in patients receiving BOTOX® have been rare.
- BOTOX Cosmetic® should only be administered by a licensed health care professional who is well trained in the anatomy of the face.

### **Safety**

- BOTOX Cosmetic® may not be the correct course of treatment for everyone. Side-effects including serious-side effects have been associated with the use of BOTOX Cosmetic®. Patients are therefore recommended to discuss these and their personal medical history with their physician prior to beginning any course of BOTOX Cosmetic® treatment.<sup>1</sup>
- With more than 2,100 articles on BOTOX® and BOTOX Cosmetic® in peer-reviewed publications, the product is one of the most widely researched medicines in the world and has been used safely in Canada for more than 20 years.

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- Today, BOTOX® benefits 21 different patient populations across approximately 80 countries, ranging from very debilitated and compromised patients to healthy individuals who want to look and feel their best.
- Allergan reviews the safety of all of its products on a routine basis in response to new clinical and scientific data and adverse events reports, and makes the appropriate changes to ensure optimal patient safety.

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### **For further information please contact:**

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<sup>1</sup> The following serious adverse events have been reported rarely (less than 0.1%): skin rash, itching, allergic reaction (including anaphylaxis), dysphagia, respiratory compromise, seizures, and facial paralysis. There have also been rare reports after botulinum toxin treatment of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors, including cardiovascular disease. (Updated BOTOX Cosmetic product monograph by Health Canada, page 24)

