

Background

STRABISMUS

What is strabismus?

Strabismus is a visual defect that results when the eyes do not properly align with each other. One eye may look straight ahead but the other may turn in (“crossed eyes”), out (“wall eyes”), upward, or downward. Strabismus usually develops during childhood but can occur at any age, affecting nearly four in every 100 adults.¹ The misalignment of the eye may be constant, or may come and go, but does not often resolve without medical intervention.

Left untreated, strabismus can result in serious vision problems. Normally both eyes focus on the same spot, and the brain processes these similar pictures into a single, three-dimensional image. Because the eyes of a patient suffering from strabismus look in different directions, the brain receives different images from each eye. As a result, the brain tries to compensate for this “double vision” by suppressing the input from one eye, impairing depth perception. Over time the brain may “forget” how to interpret signals from the eye it is ignoring, eventually leading to vision loss or functional blindness in the affected eye, a condition called amblyopia (decreased vision). Strabismus is often accompanied by blurred vision, headaches, eye strain, and fatigue.

What causes strabismus?

Strabismus is caused by weakness or other problems with one or more of the six extraocular muscles surrounding each eye that coordinate eye movement and position the eyes to focus in the same direction. Strabismus in childhood may be a congenital defect or may develop as a result of other conditions that interfere with eye coordination, including cerebral palsy and Down’s syndrome. Strabismus acquired in adolescence or adulthood can be caused by a disease (e.g., diabetes), neurologic disorders (e.g., brain tumor), or traumatic head injury.

Indication

BOTOX[®] is a prescription medicine that is injected into muscles and used to treat certain types of eye muscle problems (strabismus) in people 12 years and older.

IMPORTANT SAFETY INFORMATION

BOTOX[®] may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems after treatment with BOTOX[®]:

- **Problems swallowing, speaking, or breathing. These problems can happen hours to weeks after an injection of BOTOX[®]** usually because the muscles that you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with BOTOX[®].
- Swallowing problems may last for several months. People who already have swallowing or breathing problems before receiving BOTOX[®] have the highest risk of getting these problems.
- **Spread of toxin effects.** In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include: loss of strength and muscle weakness all over the body, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice (dysphonia), trouble saying words clearly (dysarthria), loss of bladder control, trouble breathing, trouble swallowing.

Please see next page for additional Important Safety Information.

How is strabismus treated?

Patients with strabismus are generally referred to ophthalmologists for treatment. Strabismus treatment focuses on strengthening the eye muscles to improve alignment and achieve normal vision in both eyes. Glasses and eye exercises may be prescribed. When amblyopia is present (as is often the case in children with strabismus) the “good” eye may be covered with a patch forcing the child to use and train the amblyotic eye. If strengthening techniques are unsuccessful, surgery to reposition the extraocular muscles may be considered.

Therapy with BOTOX[®] (onabotulinumtoxinA) provides a minimally-invasive alternative to surgery for appropriate strabismus patients. BOTOX[®] is a prescription medicine that is injected into muscles and used to treat strabismus in people 12 years of age and older, and involves the injection of small therapeutic doses of purified botulinum toxin protein directly into the muscles surrounding the eye. Derived from the bacterium *Clostridium botulinum*, BOTOX[®] therapy inhibits the release of a neurotransmitter, acetylcholine, from nerve cells, blocking the signals that promote involuntary muscle contractions. The effect is temporary and the treatment needs to be readministered approximately every one to three months depending on the individual patient.

IMPORTANT SAFETY INFORMATION (continued)

These symptoms can happen hours to weeks after you receive an injection of BOTOX[®].

These problems could make it unsafe for you to drive a car or do other dangerous activities. See "What should I avoid while receiving BOTOX[®]" in Medication Guide.

There has not been a confirmed serious case of spread of toxin effect away from the injection site when BOTOX[®] has been used at the recommended dose to treat severe underarm sweating, blepharospasm, or strabismus, or when BOTOX[®] Cosmetic has been used at the recommended dose to treat frown lines.

Tell your doctor about all your medical conditions, including if you have: a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome).

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal products.

For further information please contact Allergan, Inc.:

Caroline Van Hove: 714-246-5134

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BOTOX[®] can cause serious side effects. Other side effects of BOTOX[®] include: dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, and eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, and dry eyes.

Symptoms of an allergic reaction to BOTOX[®] may include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of BOTOX[®]. For more information, ask your doctor or pharmacist.

For additional information refer to Medication Guide. This Medication Guide summarizes the most important information about BOTOX[®]. If you would like more information, talk with your doctor.

Please see the accompanying full Product Information, including Medication Guide, for BOTOX[®].

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ⁱ EyeCare America (A program of the Foundation of the American Academy of Ophthalmology); Strabismus. Accessed October 1, 2009.
Available at: <http://www.eyecareamerica.org/eyecare/conditions/strabismus/index.cfm>.