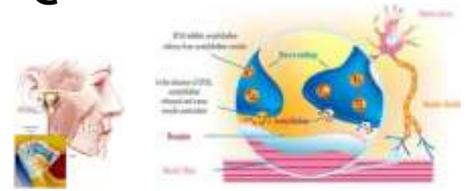


Rx **BOTULIN TOXIN**  
(BOTULINUM TOXIN - INJECTION (BOTT-you-lie-num))



**GENERIC NAME:** BOTULINUM TOXIN - INJECTION (BOTT-you-lie-num)

**USES**

There are different types of botulinum toxin products (toxin A and B) with different uses (eye problems, muscle spasms, cosmetic). Different brands of this medication deliver different amounts of medication. Your doctor will choose the correct product for you. Botulinum toxin is used to treat certain eye disorders such as crossed eyes (strabismus) and uncontrolled blinking (blepharospasm), to treat muscle spasms or movement disorders (such as cervical dystonia, torticollis), and to reduce the cosmetic appearance of wrinkles. Botulinum toxin relaxes muscle by blocking the release of a chemical called acetylcholine. It is also used to treat severe underarm sweating. Botulinum toxin works by blocking the chemicals that turn on the sweat glands. Botulinum toxin is not a cure, and your symptoms will gradually return as the medication wears off.

**HOW TO USE**

Read the Medication Guide and, if available, the Patient Information Leaflet provided by your pharmacist before you start using this medication and each time you get an injection. If you have any questions regarding the information, consult your doctor or pharmacist. This medication is given by injection by an experienced health care professional. It is injected into the affected muscles (intramuscularly) when treating eye disorders, muscle spasms and wrinkles. It is injected into the skin (intradermally) for the treatment of excessive sweating. Your dose, the number of injections, the site of injections, and how often you receive the medication will be determined by your condition and your response to therapy. Most people start to see an effect within a few days to 2 weeks, and the effect usually lasts 3 to 6 months.

**SIDE EFFECTS**

Because this medication is given at the site of your condition, most of the side effects occur close to where the medication is injected. Redness, bruising, infection, and pain at the injection site may occur. Dizziness, mild difficulty swallowing, respiratory infections such as cold or flu, pain, nausea, headache, and muscle weakness may occur when this medication is used to relax muscles. Double vision, drooping or swollen eyelid, eye irritation, dry eyes, tearing, reduced blinking, and increased sensitivity to light may also occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. You may require protective eye drops/ointments, an eye patch, or other treatment. When this medication is used for excessive sweating, side effects such as non-underarm sweating, respiratory infections such as cold or flu, headache, fever, neck or back pain, and anxiety may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: itching/swelling (especially of the face/tongue/throat), rash, severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

**PRECAUTIONS**

Before using this medication, tell your doctor your medical history, especially of: any allergies, bleeding problems, eye surgery, certain eye problem (glaucoma), heart disease, signs of infection near the injection site, muscle/nerve disorders such as Lou Gehrig's disease (ALS) or myasthenia gravis, seizures, trouble swallowing (dysphagia), pneumonia (aspiration-type). This drug may make cause muscle weakness, droopy eyelids, or blurred vision. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely. Limit alcoholic beverages. Before having surgery, tell your doctor or dentist that you are using this medication. Caution is advised if using this drug in children for muscle spasms, because they may be more sensitive to its possible side effects (such as difficulty breathing or swallowing). See Warning section. Discuss the risks and benefits with the doctor. This medication should be used only if clearly needed during pregnancy. Discuss the risks and benefits with your doctor. Use for the cosmetic treatment of wrinkles is not recommended during pregnancy. It is not known whether this medication passes into breast milk. Consult your doctor before breast-feeding.

**DRUG INTERACTIONS**

Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: certain antibiotics (e.g., aminoglycosides such as gentamicin, polymyxin), anticoagulants (e.g., warfarin), Alzheimer's disease drugs (e.g., donepezil, galantamine, rivastigmine, tacrine), myasthenia gravis drugs (e.g., ambenonium, pyridostigmine), quinidine. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

**OVERDOSE**

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. An antitoxin is available but must be used before symptoms of overdose become apparent. Symptoms of overdose may be delayed, and may include serious muscle weakness, breathing problems and paralysis.

**STORAGE**

This medication must be stored properly. Store unopened vials of the US medication in a refrigerator between 36-46 degrees F (2-8 degrees C). The diluted solution should be refrigerated at 36-46 degrees F (2-8 degrees C) and used within 4 hours once it has been prepared. Do not store in the bathroom. Keep this and all medications out of the reach of children and pets. Different brands of this medication have different storage needs (before and after mixing). Check the product package for instructions on how to store your brand, or ask your pharmacist. Keep all medications away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

**WARNING:** See also Uses section.

This medication can spread to other parts of the body after your injection, causing serious (possibly fatal) side effects. These can occur hours or even weeks after the injection. However, the chances of such serious side effects occurring when this medication is used for skin conditions such as wrinkles, eye spasm, or excessive sweating are extremely unlikely.

Children being treated for muscle spasms have the greatest risk of these effects, as well as anyone that has certain medical conditions (see Precautions section). Discuss the risks and benefits of this medication with your doctor.

Seek immediate medical attention if any of these rare but very serious side effects occur: chest pain, difficulty breathing, excessive muscle weakness, irregular heartbeat, severe difficulty swallowing or speaking, loss of bladder control.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



**Taj Group of Companies** <sup>INDIA</sup>

**Taj Pharmaceuticals Ltd.**

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91,  
(0)22 - 26374592/93 91 - (0)22 - 30601000,  
Fax : 91-(0)22-26341274

Revised November 2010