

Migraine and Neurogenic Pain Center at PIERCEY NEUROLOGY LLC

650 SW 3rd Street, Corvallis OR 97333-4437

Phone: 541-207-3900, Fax: 541-207-3232

<http://www.pierceyneurology.com>

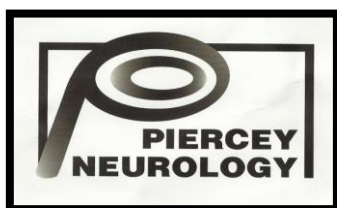
Botulinum Toxin Treatment for Headache

Botox is the most recognized name in Toxin therapy as it was originally licensed in the 1970s for treating blepharospasm and nystagmus (both eye disorders) in children, but in recent years it has become renowned for its cosmetic properties. However, it is also growing in popularity due to the recent discoveries of additional medical benefits. This includes the use of Toxin in reducing the frequency and severity of headaches and migraines. Now several brands of Toxin therapy (Botox, Dysport and Xeomin are used at PIERCEY NEUROLOGY LLC) are available allowing optimal management tailored to individual patients.

The link between the use of Toxin and a reduction in headaches first became apparent when people undertaking treatment for the reduction of frown lines reported that they were suffering from migraines and headaches far less frequently until the effects of treatment have worn off. There is no definitive answer as to why Toxin has this effect. Toxin blocks the release of the neurotransmitter in a localized site, thus preventing the nerves from relaying brain signals to the muscle and causing temporary paralysis. Therefore one theory is that the relaxing of the muscle reduces the tension that can trigger headaches in some sufferers. Another hypothesis is that the toxin prevents the transmission of pain signals to the brain, reducing the severity of the headache.

Over a period of time, the nerves will form new connections and start relaying brain signals once more, meaning the effects of Toxin treatment are only temporary. The duration of these effects varies between individuals, but if you receive Toxin for the purpose of reducing headaches or migraines you can expect the results to last for between 3 and 6 months.

Toxin is considered to be a relatively safe procedure. Unwanted side effects such as soreness around the injection site, slight bruising and nausea affect less than 10 percent of patients. If your doctor has recommended Toxin as a treatment to diminish the frequency of your headaches you should also be made aware that in a very small number of cases drooping of the brow can occur. This happens when the administered dose of Toxin is too high. Thankfully, this condition is only temporary and the problem should correct itself as the effects of the Toxin wear off over the course of several weeks.



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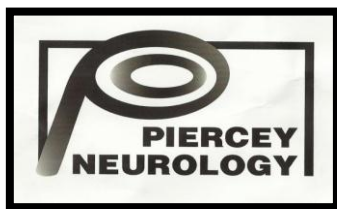
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Why is this botulinum toxin prescribed?

Botulinum Toxin injections are in a class of medications called neurotoxins. When Botulinum Toxin is injected into a muscle, it blocks the nerve signals that cause uncontrollable tightening and movements of the muscle. When Botulinum Toxin is injected into a sweat gland, it decreases the activity of the gland to reduce sweating. Botulinum Toxin injection is used to relieve the symptoms of:

- Cervical dystonia (spasmodic torticollis; uncontrollable tightening of the neck muscles that may cause neck pain and abnormal head positions) in people 16 years of age and older;
- Strabismus (an eye muscle problem that causes the eye to turn inward or outward) and
- Blepharospasm (uncontrollable tightening of the eyelid muscles that may cause blinking, squinting, and abnormal eyelid movements) in people 12 years of age and older.
- Headaches in people older than 18 years of age with chronic migraine (severe, throbbing headaches that are sometimes accompanied by nausea and sensitivity to sound or light) who have 15 or more days each month with headaches lasting 4 hours or more.
- Incontinence (leakage of urine) in people 18 years of age and older with overactive bladder (condition in which the bladder muscles have uncontrollable spasms) caused by nerve problems such as spinal cord injury or multiple sclerosis (MS; a disease in which the nerves do not function properly and people may experience weakness, numbness, loss of muscle coordination, and problems with vision, speech, and bladder control), who cannot be treated with oral medication.
- Limb spasticity (increased muscle stiffness) in the elbow, wrist, and fingers in people 18 years of age and older; and to treat severe underarm sweating in people 18 years of age and older who cannot be treated with products applied on the skin.
- Smooth frown lines (wrinkles between the eyebrows) in adults up to 65 years of age.
- Hyperhidrosis (problematic underarm sweating) in adults.



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How should this medicine be used?

Botulinum Toxin injection is reconstituted as a liquid and injected into a muscle, into the skin, or into the wall of the bladder by a doctor. Your doctor will choose the best place to inject the medication in order to treat your condition. If you are receiving Botulinum Toxin to treat frown lines, cervical dystonia, blepharospasm, strabismus, upper limb spasticity, urinary incontinence, or chronic migraine, you may receive additional injections every 3 to 4 months, depending on your condition and on how long the effects of the treatment last. If you are receiving Botulinum Toxin injection to treat severe underarm sweating, you may need to receive additional injections once every 6 to 7 months or when your symptoms return.

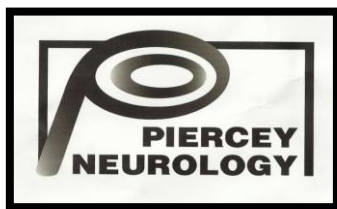
If you are receiving Botulinum Toxin injection to treat severe underarm sweating, your doctor will probably perform a test to find the areas that need to be treated. Your doctor will tell you how to prepare for this test. You will probably be told to shave your underarms and not to use nonprescription deodorants or antiperspirants for 24 hours before the test.

Your doctor may change your dose of Botulinum Toxin injection to find the dose that will work best for you.

Your doctor may use an anesthetic cream, or a cold pack, to numb your skin, or eye drops to numb your eyes before injecting Botulinum Toxin.

If you are receiving Botulinum Toxin injection to treat urinary incontinence, your doctor may prescribe antibiotics for you to take for 1–3 days before your treatment, on the day of your treatment and for 1 to 3 days after your treatment.

There are three brands of botulinum toxin used at PIERCEY NEUROLOGY: Botox, Dysport and Xeomin. Your provider will determine the brand of botulinum toxin recommended best for you and this brand will be used during the course of your treatment as one brand or type of botulinum toxin cannot be substituted for another. That being said at times it may be recommended to switch brands of botulinum toxin to maximize clinical effect or minimize side effects. If this is done you will be notified and now this brand of botulinum toxin will be used for you during subsequent treatments.



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Botulinum Toxin injection may help control your condition but will not cure it. It may take a few days or up to several weeks before you feel the full benefit of Botulinum Toxin injection. Ask your doctor when you can expect to see improvement, and call your doctor if your symptoms do not improve during the expected time.

Other uses for this medicine

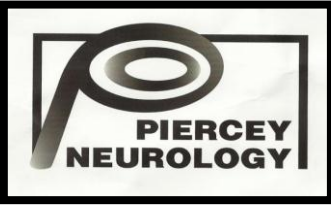
Botulinum Toxin injection is also sometimes used to treat other conditions in which abnormal muscle tightening causes pain, abnormal movements, or other symptoms. Botulinum Toxin injection is also sometimes used to treat excessive sweating of the hands, excessive sweating that occurs during or after eating, many types of wrinkles of the face, tremor (uncontrollable shaking of a part of the body), and anal fissures (a split or tear in the tissue near the rectal area). The medication is also sometimes used to improve the ability to move in children with cerebral palsy (condition that causes difficulty with movement and balance) or adults who have had a stroke. Talk to your doctor about the risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

IMPORTANT WARNING:

Botulinum Toxin injection is given as a number of tiny injections intended to affect only the specific area where injected. However, it is possible that the medication may spread from the area of injection and affect muscles in other areas of the body. If the muscles that control breathing and swallowing are affected, you may develop severe problems breathing or swallowing that may last for several months and may cause death. If you have difficulty swallowing, you may need to be fed through a feeding tube to avoid getting food or drink into your lungs.

Botulinum Toxin injection may spread and cause symptoms in people of any age who are being treated for any condition, although no one has yet developed these symptoms after receiving the medication at recommended doses to treat wrinkles, eye problems, headaches, or severe underarm sweating. The risk that the medication will spread beyond



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the area of injection is probably highest in children being treated for abnormal muscle tightening and in people, who have or have ever had swallowing problems, or breathing problems, such as asthma or emphysema; or any condition that affects muscles or nerves such as amyotrophic lateral sclerosis (ALS, Lou Gehrig's disease; condition in which the nerves that control muscle movement slowly die, causing the muscles to shrink and weaken), motor neuropathy (condition in which the muscles weaken over time), myasthenia gravis (condition that causes certain muscles to weaken, especially after activity), or Lambert-Eaton syndrome (condition that causes muscle weakness that may improve with activity). Tell your doctor if you have or have ever had any of these conditions.

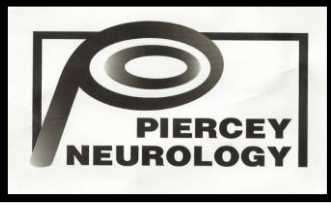
Spread of Botulinum Toxin injection into untreated areas can cause other symptoms in addition to difficulty breathing or swallowing. Symptoms may occur within hours of an injection or as late as several weeks after treatment. If you experience any of the following symptoms, call your doctor immediately or get emergency medical treatment: loss of strength or muscle weakness all over the body; double or blurred vision; drooping eyelids; difficulty swallowing or breathing; hoarseness or change or loss of voice; difficulty saying words clearly; or inability to control urination.

Your provider at PIERCEY NEUROLOGY will have available the manufacturer's patient information sheet (Medication Guide) for you when you begin treatment with Botulinum Toxin injection and each time you receive treatment. We recommend you read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>) or the manufacturer's website to obtain the Medication Guide.

What special precautions should I follow?

Before receiving Botulinum Toxin injection,

- Tell your doctor and pharmacist if you are allergic to Botulinum Toxin, abobotulinumtoxinA (Dysport), incobotulinumtoxinA (Xeomin), rimabotulinumtoxinB (Myobloc); any other medications; or any of the ingredients in



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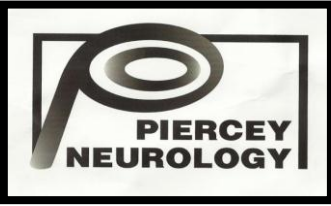
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Botulinum Toxin injection. Ask your pharmacist or check the Medication Guide for a list of the ingredients.

- Tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: certain antibiotics such as amikacin, clindamycin (Cleocin), colistimethate (Coly-Mycin), gentamicin, kanamycin, lincomycin (Lincocin), neomycin (Neo-Fradin, Neo-Rx), polymyxin, streptomycin, and tobramycin (Tobi); anticoagulants ('blood thinners') such as warfarin (Coumadin); antihistamines; aspirin and other nonsteroidal anti-inflammatory medications (NSAIDs) such as ibuprofen (Advil, Motrin) and naproxen (Aleve, Naprosyn); cholinesterase inhibitors such as ambenonium (Mytelase), donepezil (Aricept), galantamine (Razadyne), neostigmine (Prostigmin), physostigmine, pyridostigmine (Mestinon, Regonol), rivastigmine (Exelon), and tacrine (Cognex); heparin; ipratropium (Atrovent); magnesium sulfate; medications for allergies, colds, or sleep; medications for glaucoma, inflammatory bowel disease, motion sickness, Parkinson's disease, ulcers, or urinary problems; muscle relaxants; platelet inhibitors such as clopidogrel (Plavix), dipyridamole (Persantine, in Aggrenox), prasugrel (Effient), and ticlopidine (Ticlid); and quinidine. Also tell your doctor if you have received injections of any botulinum toxin product within the past four months. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- Tell your doctor if you have swelling or other signs of infection or weakness in the area where Botulinum Toxin will be injected. Your doctor will not inject the medication into an area that is infected or weak.
- If you will be receiving Botulinum Toxin injection to treat urinary incontinence, tell your doctor if you have a urinary tract infection (UTI), which may include symptoms such as pain or burning when you urinate, frequent urination, or fever; or if you have urinary retention (inability to fully empty the bladder) and do not regularly empty your bladder with a catheter. Your doctor will probably not treat you with Botulinum Toxin injection.
- Tell your doctor if you have ever had any side effect from any botulinum toxin product, or eye or face surgery, and if you have or have ever had bleeding problems; seizures; or hyperthyroidism (a condition that occurs when the thyroid gland produces too much thyroid hormone).



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- If you will be receiving Botulinum Toxin injection to treat wrinkles, your doctor will examine you to see if the medication is likely to work for you. Botulinum Toxin injection may not smooth your wrinkles or may cause other problems if you have drooping eyelids; trouble raising your eyebrows; excess skin on your eyelids; deeply scarred, thick, or oily skin; or if your wrinkles cannot be smoothed by spreading them apart with your fingers.
- Tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while receiving Botulinum Toxin injection, call your doctor.
- If you are having surgery, including dental surgery, tell the doctor or dentist that you are receiving Botulinum Toxin injection.
- You should know that Botulinum Toxin injection may cause loss of strength or muscle weakness all over the body or impaired vision. If you have any of these symptoms, do not drive a car, operate machinery, or do other dangerous activities.

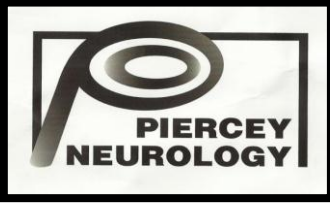
What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What side effects can this medication cause?

Botulinum Toxin injection may cause side effects. Ask your doctor which side effects you are most likely to experience, since some side effects may occur more often in the part of the body where you received the injection. Tell your doctor if any of these symptoms are severe or do not go away:

- pain, tenderness, swelling, redness, bleeding, or bruising in the place where you received the injection
- tiredness
- headache
- drowsiness
- muscle pain, stiffness, tightness, weakness, or spasm
- pain or tightness in the face or neck
- dry mouth
- nausea



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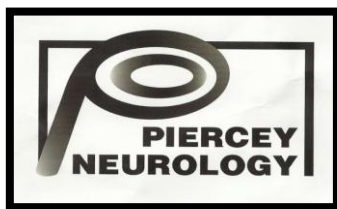
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- constipation
- anxiety
- dry or irritated eyes
- teary eyes
- difficulty closing the eyes
- difficulty falling asleep or staying asleep
- sweating from parts of the body other than the underarms

Some side effects can be serious. If you experience any of these symptoms, or those listed in the IMPORTANT WARNING section, at any time during the first several weeks after your treatment, call your doctor immediately or get emergency medical treatment:

- double, blurred, or decreased vision
- eyelid swelling
- dry, irritated, or painful eyes
- difficulty moving the face
- seizures
- irregular heartbeat
- chest pain
- pain in the arms, back, neck, or jaw
- shortness of breath
- fainting
- dizziness
- rash
- hives
- itching
- swelling of the hands, feet, ankles, or lower legs
- inability to empty your bladder on your own
- pain or burning when urinating or frequent urination
- blood in urine
- fever

Botulinum Toxin injection may cause other side effects. Call your doctor if you have any unusual problems while receiving this medication.



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If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/Safety/MedWatch>] or by phone [1-800-332-1088].

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose usually do not appear right after receiving the injection. If you received too much Botulinum Toxin or if you swallowed the medication, tell your doctor right away and also tell your doctor if you experience any of the following symptoms during the next several weeks:

- weakness
- difficulty moving any part of your body
- difficulty breathing
- difficulty swallowing

What other information should I know?

Keep all appointments with your doctor.

Ask your pharmacist any questions you have about Botulinum Toxin injection.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

MIGRAINES CALENDAR

MIGRAINE AND NEUROGENIC PAIN CENTER AT PIERCEY NEUROLOGY LLC

Sun	Mon	Tue	Wed	Thu	Fri	Sat

RECORD:

1. THE DAYS YOU HAVE A MIGRAINE.
2. ITS INTENSITY (IE CAN USE 1 - 10 SCALE...OR ANY SCALE THAT MAKES SENSE).
3. WHAT TREATMENT YOU USED; WHETHER THE TREATMENT WAS EFFECTIVE.



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