Drugs.com
Know more. Be sure.

onabotulinumtoxinA

Generic Name: onabotulinumtoxinA (Botox) (ON a BOT ue LYE num TOX in A)
Brand Name: *Botox, Botox Cosmetic*

What is onabotulinumtoxinA (Botox)?

OnabotulinumtoxinA (Botox), also called botulinum toxin type A, is made from the bacteria that causes botulism. Botulinum toxin blocks nerve activity in the muscles, causing a temporary reduction in muscle activity.

Botox is used to treat cervical dystonia (severe spasms in the neck muscles). Botox is also used to treat muscle spasms (stiffness) in the upper limbs (elbows, wrists, fingers) or lower limbs (ankles, toes). Botox is also used to treat severe underarm sweating (hyperhidrosis).

Botox is also used to treat certain eye muscle conditions caused by nerve disorders. This includes uncontrolled blinking or spasm of the eyelids, and a condition in which the eyes do not point in the same direction.

Botox is also used to treat overactive bladder and incontinence (urine leakage) caused by nerve disorders such as spinal cord injury or multiple sclerosis.

Botox is also used to prevent chronic migraine headaches in adults who have migraines for more than 15 days per month, each lasting 4 hours or longer. Botox should not be used to treat a common tension headache.

Botox Cosmetic is used to temporarily lessen the appearance of facial wrinkles.

Botox may also be used for other purposes not listed in this medication guide.

What is the most important information I should know about Botox?

You should not use Botox if you have an infection in the area where the medicine will be injected. Botox should not be used for overactive bladder or incontinence if you have a bladder infection or you are unable to urinate (unless you routinely use a catheter).

The botulinum toxin contained in this medicine can spread to other body areas beyond where it was injected. This can cause serious life-threatening side effects.

Call your doctor at once if you have a hoarse voice, drooping eyelids, vision problems, severe muscle weakness, loss of bladder control, or trouble breathing, talking, or swallowing. Some of these effects can occur up to several hours or several weeks after an injection.

What should I discuss with my healthcare provider before I receive Botox?

You should not receive this medication if you are allergic to botulinum toxin, or if you have:

- an infection in the area where the medicine will be injected; or
- (for overactive bladder and incontinence) if you have a current bladder infection or if you are unable to urinate and you do not routinely use a catheter.

To make sure Botox is safe for you, tell your doctor if you have:

- amyotrophic lateral sclerosis (ALS, or "Lou Gehrig's disease");
- myasthenia gravis;
- Lambert-Eaton syndrome;

- a breathing disorder such as asthma or emphysema;
- problems with swallowing;
- facial muscle weakness (droopy eyelids, weak forehead, trouble raising your eyebrows);
- a change in the normal appearance of your face;
- bleeding problems;
- heart disease;
- if you have had or will have surgery (especially on your face);
- if you have recently used a blood thinner (warfarin, Coumadin, and others) or been treated with an injectable antibiotic;
- if you have ever received other botulinum toxin injections such as Dysport or Myobloc (especially in the last 4 months); or
- if you have ever had a side effect after receiving a botulinum toxin in the past.

Botox is made from human plasma (part of the blood) which may contain viruses and other infectious agents. Donated plasma is tested and treated to reduce the risk of it containing infectious agents, but there is still a small possibility it could transmit disease. Talk with your doctor about the risks and benefits of using this medication.

It is not known whether this medicine will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant.

Botox can pass into breast milk and may harm a nursing baby. Tell your doctor if you are breast-feeding a baby.

How is Botox given?

Botulinum toxin injections **should be given only by a trained medical professional**, even when used for cosmetic purposes.

This medicine is injected into a muscle. A doctor, nurse, or other healthcare provider will give you this injection. Botox injections should be spaced at least 3 months apart.

Your injection may be given into more than one area at a time, depending on the condition being treated.

While receiving botulinum toxin injections for an eye muscle conditions, you may need to use eye drops, ointment, a special contact lens or other device to protect the surface of your eye. Follow your doctor's instructions.

If you are being treated for excessive sweating, shave your underarms about 24 hours before you will receive your injection. Do not apply underarm antiperspirants or deodorants for 24 hours before you receive the injection. Avoid exercise and hot foods or beverages within 30 minutes before the injection.

It may take up to 2 weeks after injection before neck muscle spasm symptoms begin to improve. You may notice the greatest improvement at 6 weeks after injection.

It may take only 1 to 3 days after injection before eye muscle spasm symptoms begin to improve. You may notice the greatest improvement at 2 to 6 weeks after injection.

The effects of a Botox injection are temporary. Your symptoms may return completely within 3 months after an injection. After repeat injections, it may take less and less time before your symptoms return, especially if your body develops antibodies to the botulinum toxin.

Do not seek botulinum toxin injections from more than one medical professional at a time. If you switch healthcare providers, be sure to tell your new provider how long it has been since your last botulinum toxin injection.

Using this medication more often than prescribed will not make it more effective and may result in serious side effects.

What happens if I miss a dose?

Since botulinum toxin has a temporary effect and is given at widely spaced intervals, missing a dose is not likely to be harmful.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

Overdose symptoms may not appear right away, but can include muscle weakness, trouble swallowing, and weak or shallow breathing.

What should I avoid after receiving Botox?

Botox may impair your vision or depth perception. Be careful if you drive or do anything that requires you to be able to see clearly.

Avoid using underarm antiperspirants or deodorants for 24 hours after a botulinum toxin injection if you are being treated for excessive underarm sweating.

Avoid going back to your normal physical activities too quickly after receiving an injection.

Botox side effects

Get emergency medical help if you have **signs of an allergic reaction:** hives; difficult breathing; feeling like you might pass out; swelling of your face, lips, tongue, or throat.

The botulinum toxin contained in Botox can spread to other body areas beyond where it was injected. This has caused serious life-threatening side effects in some people receiving botulinum toxin injections, even for cosmetic purposes.

Call your doctor at once if you have any of these side effects, some of which can occur up to several hours or several weeks after an injection:

- unusual or severe muscle weakness (especially in a body area that was not injected with the medication);
- trouble breathing, talking, or swallowing;
- hoarse voice, drooping eyelids;
- loss of bladder control;
- eyelid swelling, crusting or drainage from your eyes, problems with vision;
- pain or burning when you urinate, little or no urinating; or
- chest pain, irregular heartbeats.

Common side effects may include:

- trouble swallowing for several months after treatment;
- muscle weakness near where the medicine was injected;
- bruising, bleeding, pain, redness, or swelling where the injection was given;
- headache, tiredness, muscle stiffness, neck or back pain, pain in your arms or legs;
- dry mouth, blurred vision;
- increased sweating in areas other than the underarms; or
- cold symptoms such as stuffy nose, sneezing, cough, sore throat, flu symptoms.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

See also: Side effects (in more detail)

OnabotulinumtoxinA dosing information

Usual Adult Dose for Blepharospasm:

OnabotulinumtoxinA (Botox(R)):
1.25 to 2.5 units IM (0.05 mL to 0.1 mL volume at each site) injected into the medial and lateral pretarsal orbicularis oculi of the upper lid and into the lateral pretarsal orbicularis oculi of the lower lid

Comments:
-Reconstituted solution is injected using a sterile, 27 to 30 gauge needle without electromagnetic guidance:
-Avoiding injection near the levator palpebrae superioris may reduce the complication of ptosis.
-Avoiding medial lower lid injections, and thereby reducing diffusion into the inferior oblique, may reduce the complication of diplopia.
-Ecchymosis occurs easily in the soft eyelid tissues. This can be prevented by applying pressure at the injection site immediately after the injection.
-The cumulative dose of this drug in a 30 day period should not exceed 200 units.
-The initial effect of the injections is usually seen within 3 days and reaches a peak at 1 to 2 weeks posttreatment. Each treatment lasts approximately 3 months, after which the procedure may be repeated. At repeat treatment sessions, the dose may be increased up to 2-fold if the response from the initial treatment is considered insufficient (usually defined as an effect that does not last longer than 2 months). However, there appears to be little benefit obtainable from injecting more than 5 units per site. Injecting more frequently than every 3 months may result in some tolerance, and is rare to have the effect be permanent.
-When initiating treatment, the lowest recommended dose should be used. In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 units in a 3 month interval.
-Caution should be exercised when treatment 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(s).

Use: Treatment of blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older

Usual Adult Dose for Strabismus:

OnabotulinumtoxinA (Botox(R)):
Use the lower listed doses for treatment of small deviations. Use the larger doses only for large deviations:
-For vertical muscles, and for horizontal strabismus of less than 20 prism diopters: 1.25 to 2.5 units IM in any one muscle
-For horizontal strabismus of 20 prism diopters to 50 prism diopters: 2.5 to 5 units IM in any one muscle
-For persistent VI nerve palsy of one month or longer duration: 1.25 to 2.5 units IM in the medial rectus muscle

Subsequent doses for residual or recurrent strabismus: It is recommended that patients be reexamined 7 to 14 days after each injection to assess the effect of that dose:
-Patients experiencing adequate paralysis of the target muscle that require subsequent injections should receive a dose comparable to the initial dose.
-Subsequent doses for patients experiencing incomplete paralysis of the target muscle may be increased up to 2-fold compared to the previously administered dose.
-Subsequent injections should not be administered until the effects of the previous dose have dissipated as evidenced by substantial function in the injected and adjacent muscles.
-The maximum recommended dose as a single injection for any one muscle is 25 units.

Comments:
-This drug is intended for injection into extraocular muscles utilizing the electrical activity recorded from the tip of the injection needle as a guide to placement within the target muscle. Injection without surgical exposure or electromyographic guidance should not be attempted. Physicians should be familiar with electromyographic technique.
-To prepare the eye for injection, it is recommended that several drops of a local anesthetic and an ocular decongestant be given several minutes prior to injection.
-Paralysis of injected muscles typically occurs 1 to 2 days after the initial injection, lasts 2 to 6 weeks, and resolves over a similar time period. Overcorrections lasting more than 6 months have been rare. About one-half of patients will require subsequent doses because of inadequate paralytic response of the muscle to the initial dose, or because of mechanical factors such as large deviations or restrictions, or because of the lack of binocular motor fusion to stabilize the alignment.
-When initiating treatment, the lowest recommended dose should be used. In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 units in a 3 month interval.
-Caution should be exercised when treatment 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(s).

Use: Treatment of strabismus in patients 12 years of age or older

Usual Adult Dose for Upper Limb Spasticity:

OnabotulinumtoxinA (Botox(R)):
In clinical trials, doses of onabotulinumtoxinA ranging from 75 units to 400 units were divided among selected muscles at a given treatment session:
Recommended dose ranges per muscle:
Biceps Brachii: 100 to 200 units divided in 4 sites
Flexor Carpi Radialis: 12.5 to 50 units in 1 site
Flexor Carpi Ulnaris: 12.5 to 50 units in 1 site
Flexor Digitorum Profundus: 30 to 50 units in 1 site
Flexor Digitorum Sublimis: 30 to 50 units in 1 site
Adductor Pollicis: 20 units in 1 site
Flexor Pollicis Longus: 20 units in 1 site

Comments:
-Repeat treatment may be administered when the effect of a previous injection has diminished, but generally no sooner than 12 weeks after the previous injection. The degree and pattern of muscle spasticity at the time of re-injection may necessitate alterations in the dose muscles to be injected.
-When initiating treatment, the lowest recommended dose should be used. In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 units in a 3 month interval.
-Caution should be exercised when treatment 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(s).
-This drug has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.
-Treatment is not intended to substitute for usual standard of care rehabilitation regimens.
-Safety and effectiveness have not been established for the treatment of other upper limb muscle groups, or for the treatment of lower limb spasticity.
-Safety and effectiveness have not been established for the treatment of spasticity in pediatric patients under age 18 years.

Use:
-For the treatment of upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris), finger flexors (flexor digitorum profundus and flexor digitorum sublimis), and thumb flexors (adductor pollicis and flexor pollicis longus).

Usual Adult Dose for Cervical Dystonia:

OnabotulinumtoxinA (Botox(R)):
-In a study of patients who had previously received and tolerated this drug, the mean dose administered was 236 units (25 th to 75 th percentile range 198 to 300 units) divided among the affected muscle groups

Comments:
-Dosing in initial and sequential treatment sessions should be tailored to the individual patient based on the patient head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history.
-The initial dose for a patient without prior use of this drug should be a lower dose, with subsequent dosing adjusted based on individual response.
-Limiting the total dose injected into the sternocleidomastoid muscle to 100 units or less may decrease the occurrence of dysphagia.
-Improvement generally begins within the first 2 weeks after injection with maximum benefit at approximately 6 weeks post-injection. Most subjects were observed to have returned to pre-treatment status by 3 months post-treatment.
-When initiating treatment, the lowest recommended dose should be used. In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 units in a 3 month interval.
-Caution should be exercised when treatment 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(s).

Use: For the treatment of adults and children over 16 years of age with cervical dystonia, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia

Usual Adult Dose for Hyperhidrosis:

OnabotulinumtoxinA (Botox):
50 units intradermally in 0.1 to 0.2 mL aliquots to each axilla distributed evenly in multiple sites (10 to 15) approximately 1 to 2 cm apart

Comments:
-The hyperhidrotic area to be injected should be defined using standard staining techniques, (e.g., Minor's Iodine-Starch Test).
-Patients should shave underarms and abstain from use of over-the-counter deodorants or antiperspirants for 24 hours prior to the test. Patient should be resting without exercise or hot drinks for 30 minutes prior to the test. Dry the underarm area and then immediately paint it with iodine solution. Allow the area to dry, then lightly sprinkle the area with starch powder. Gently blow off any excess. The hyperhidrotic area will develop a deep blue-black color over approximately 10 minutes.
-Each injection site has a ring of effect of up to approximately 2 cm in diameter.
-Repeat injections for hyperhidrosis should be administered when the clinical effect of a previous injection diminishes.
-Inject each dose to a depth of approximately 2 mm and at a 45 degree angle to the skin surface with the bevel side up.
-If injection sites are marked in ink do not inject directly through the ink mark to avoid a permanent tattoo mark.
-Safety and effectiveness for hyperhidrosis in other body areas have not been established.
-Weakness of hand muscles and blepharoptosis may occur in patients who receive this drug for palmar hyperhidrosis and facial hyperhidrosis, respectively. Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease.
Safety and effectiveness of have not been established for the treatment of axillary hyperhidrosis in pediatric patients under age 18.
-When initiating treatment, the lowest recommended dose should be used. In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 units in a 3 month interval.
-Caution should be exercised when treatment 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(s).

Use:
-Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients

Usual Adult Dose for Glabellar Lines:

OnabotulinumtoxinA (Botox (R) Cosmetic):
4 units IM into each of five sites, two in each corrugator muscle and one in the procerus muscle for a total of 20 units.

Comments:
-Refer to manufacturer information for injection site diagrams.
-To reduce the complication of ptosis the following steps should be taken:
-Avoid injection near the levator palpebrae superioris, particularly in patients with larger brow depressor complexes.
-Lateral corrugator injections should be placed at least 1 cm above the bony supraorbital ridge.
-Ensure the injected volume/dose is accurate and where feasible kept to a minimum.
-Do not inject toxin closer than 1 cm above the central eyebrow.

Use: For the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

Usual Adult Dose for Migraine Prophylaxis:

OnabotulinumtoxinA (Botox(R)):
Manufacturer recommended dosing by muscle for prophylaxis of chronic migraine:
Frontalis (bilaterally): 20 Units divided in 4 sites
Corrugator (bilaterally): 10 Units divided in 2 sites
Procerus: 5 Units in 1 site
Occipitalis (bilaterally): 30 Units divided in 6 sites

Temporalis (bilaterally): 40 Units divided in 8 sites
Trapezius (bilaterally): 30 Units divided in 6 sites
Cervical Paraspinal Muscle Group (bilaterally): 20 Units divided in 4 sites

Comments:
-When initiating treatment, the lowest recommended dose should be used. In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 units in a 3 month interval.
-Caution should be exercised when treatment 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(s).

Use: Prophylaxis of headaches in adult patients with chronic migraine (15 days or more per month with headache lasting 4 hours a day or longer).

Usual Adult Dose for Urinary Incontinence:

OnabotulinumtoxinA (Botox(R)):
GENERAL COMMENTS:
-Patients should not have an acute urinary tract infection prior to treatment. Prophylactic antibiotics (except aminoglycosides) should be administered 1 to 3 days pretreatment, on the treatment day, and 1 to 3 days posttreatment.
-Patients should discontinue antiplatelet therapy at least 3 days before the injection procedure. Patients on anticoagulant therapy should be managed appropriately to decrease the risk of bleeding.
-Appropriate caution should be exercised when performing a cystoscopy.
-When initiating treatment, the lowest recommended dose should be used. In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 units in a 3 month interval.
-Caution should be exercised when treatment 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(s).

OVERACTIVE BLADDER (OAB):
100 units per treatment

OAB COMMENTS:
-An intravesical instillation of diluted local anesthetic with or without sedation may be used prior to injection, per local site practice. If a local anesthetic instillation is performed, the bladder should be drained and irrigated with sterile saline before injection.
-Reconstituted drug is injected into the detrusor muscle via a flexible or rigid cystoscope, avoiding the trigone. The bladder should be instilled with enough saline to achieve adequate visualization for the injections, but over-distension should be avoided.
-The injection needle should be filled (primed) with approximately 1 mL of reconstituted drug prior to the start of injections (depending on the needle length) to remove any air.
-After the injections are given, patients should demonstrate their ability to void prior to leaving the clinic. The patient should be observed for at least 30 minutes post-injection and until a spontaneous void has occurred.
-Patients should be considered for reinjection when the clinical effect of the previous injection has diminished (median time until patients qualified for the second treatment about 24 weeks, but no sooner than 12 weeks from the prior bladder injection.

DETRUSOR OVER ACTIVITY ASSOCIATED WITH A NEUROLOGIC CONDITION:
200 units per treatment

DETRUSOR OVER ACTIVITY ASSOCIATED WITH A NEUROLOGIC CONDITION COMMENTS:
-An intravesical instillation of diluted local anesthetic with or without sedation, or general anesthesia may be used prior to injection. If a local anesthetic instillation is performed, the bladder should be drained and irrigated with sterile saline before injection.

Uses:
-OVERACTIVE BLADDER (OAB): Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
-DETRUSOR OVER ACTIVITY ASSOCIATED WITH A NEUROLOGIC CONDITION: Treatment of urinary incontinence due to

detrusor over activity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

Usual Adult Dose for Urinary Frequency:

OnabotulinumtoxinA (Botox(R)):
GENERAL COMMENTS:
-Patients should not have an acute urinary tract infection prior to treatment. Prophylactic antibiotics (except aminoglycosides) should be administered 1 to 3 days pretreatment, on the treatment day, and 1 to 3 days posttreatment.
-Patients should discontinue antiplatelet therapy at least 3 days before the injection procedure. Patients on anticoagulant therapy should be managed appropriately to decrease the risk of bleeding.
-Appropriate caution should be exercised when performing a cystoscopy.
-When initiating treatment, the lowest recommended dose should be used. In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 units in a 3 month interval.
-Caution should be exercised when treatment 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(s).

OVERACTIVE BLADDER (OAB):
100 units per treatment

OAB COMMENTS:
-An intravesical instillation of diluted local anesthetic with or without sedation may be used prior to injection, per local site practice. If a local anesthetic instillation is performed, the bladder should be drained and irrigated with sterile saline before injection.
-Reconstituted drug is injected into the detrusor muscle via a flexible or rigid cystoscope, avoiding the trigone. The bladder should be instilled with enough saline to achieve adequate visualization for the injections, but over-distension should be avoided.
-The injection needle should be filled (primed) with approximately 1 mL of reconstituted drug prior to the start of injections (depending on the needle length) to remove any air.
-After the injections are given, patients should demonstrate their ability to void prior to leaving the clinic. The patient should be observed for at least 30 minutes post-injection and until a spontaneous void has occurred.
-Patients should be considered for reinjection when the clinical effect of the previous injection has diminished (median time until patients qualified for the second treatment about 24 weeks, but no sooner than 12 weeks from the prior bladder injection.

DETRUSOR OVER ACTIVITY ASSOCIATED WITH A NEUROLOGIC CONDITION:
200 units per treatment

DETRUSOR OVER ACTIVITY ASSOCIATED WITH A NEUROLOGIC CONDITION COMMENTS:
-An intravesical instillation of diluted local anesthetic with or without sedation, or general anesthesia may be used prior to injection. If a local anesthetic instillation is performed, the bladder should be drained and irrigated with sterile saline before injection.

Uses:
-OVERACTIVE BLADDER (OAB): Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
-DETRUSOR OVER ACTIVITY ASSOCIATED WITH A NEUROLOGIC CONDITION: Treatment of urinary incontinence due to detrusor over activity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

Usual Adult Dose for Orbicularis Oculi:

OnabotulinumtoxinA (Botox (R) Cosmetic):
4 units IM into 3 sites per side (6 total injection points) in the lateral orbicularis oculi muscle for a total of 24 Units (12 units per side)

Comments:
-Refer to manufacturer information for injection site diagrams.

Use: For the temporary improvement in the appearance of moderate to severe lateral canthal lines associated with orbicularis oculi activity in adult patients

Usual Pediatric Dose for Strabismus:

OnabotulinumtoxinA (Botox(R)):
Use the lower listed doses for treatment of small deviations. Use the larger doses only for large deviations:
-For vertical muscles, and for horizontal strabismus of less than 20 prism diopters: 1.25 to 2.5 units IM in any one muscle
-For horizontal strabismus of 20 prism diopters to 50 prism diopters: 2.5 to 5 units IM in any one muscle
-For persistent VI nerve palsy of one month or longer duration: 1.25 to 2.5 units IM in the medial rectus muscle

Subsequent doses for residual or recurrent strabismus: It is recommended that patients be reexamined 7 to 14 days after each injection to assess the effect of that dose:
-Patients experiencing adequate paralysis of the target muscle that require subsequent injections should receive a dose comparable to the initial dose.
-Subsequent doses for patients experiencing incomplete paralysis of the target muscle may be increased up to 2-fold compared to the previously administered dose.
-Subsequent injections should not be administered until the effects of the previous dose have dissipated as evidenced by substantial function in the injected and adjacent muscles.
-The maximum recommended dose as a single injection for any one muscle is 25 units.

Comments:
-This drug is intended for injection into extraocular muscles utilizing the electrical activity recorded from the tip of the injection needle as a guide to placement within the target muscle. Injection without surgical exposure or electromyographic guidance should not be attempted. Physicians should be familiar with electromyographic technique.
-To prepare the eye for injection, it is recommended that several drops of a local anesthetic and an ocular decongestant be given several minutes prior to injection.
-Paralysis of injected muscles typically occurs 1 to 2 days after the initial injection, lasts 2 to 6 weeks, and resolves over a similar time period. Overcorrections lasting more than 6 months have been rare. About one-half of patients will require subsequent doses because of inadequate paralytic response of the muscle to the initial dose, or because of mechanical factors such as large deviations or restrictions, or because of the lack of binocular motor fusion to stabilize the alignment.
-When initiating treatment, the lowest recommended dose should be used. In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 units in a 3 month interval.
-Caution should be exercised when treatment 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(s).

Use: Treatment of strabismus in patients 12 years of age or older

Usual Pediatric Dose for Blepharospasm:

OnabotulinumtoxinA (Botox):

The safety and efficacy of onabotulinumtoxinA for the treatment of blepharospasm in children less than 12 years have not been established.

1.25 to 2.5 units (0.05 to 0.1 mL) intramuscularly each into the medial and lateral pretarsal orbicularis oculi of the upper lid and into the lateral pretarsal orbicularis oculi of the lower lid. The cumulative dose of onabotulinumtoxinA in a 30 day period should not exceed 200 units.

Approved indication: Treatment of blepharospasm associated with dystonia in patients 12 years of age or older.

Usual Pediatric Dose for Cervical Dystonia:

OnabotulinumtoxinA (Botox(R)):
-In a study of patients who had previously received and tolerated this drug, the mean dose administered was 236 units (25 th to 75 th percentile range 198 to 300 units) divided among the affected muscle groups

Comments:
-Dosing in initial and sequential treatment sessions should be tailored to the individual patient based on the patient head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history.
-The initial dose for a patient without prior use of this drug should be a lower dose, with subsequent dosing adjusted based on individual response.
-Limiting the total dose injected into the sternocleidomastoid muscle to 100 units or less may decrease the occurrence of dysphagia.
-Improvement generally begins within the first 2 weeks after injection with maximum benefit at approximately 6 weeks post-injection. Most subjects were observed to have returned to pre-treatment status by 3 months post-treatment.
-When initiating treatment, the lowest recommended dose should be used. In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 units in a 3 month interval.
-Caution should be exercised when treatment 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(s).

Use: For the treatment of children over 16 years of age with cervical dystonia, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia

What other drugs will affect Botox?

Other medicines can increase certain side effects of Botox, especially: cold or allergy medicine, muscle relaxers, sleeping pills, bronchodilators, bladder or urinary medicines, and irritable bowel medicines. Tell your doctor about all your current medicines.

Other drugs may interact with Botox, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell each of your health care providers about all medicines you use now and any medicine you start or stop using.

Where can I get more information?

- Your doctor or pharmacist can provide more information about Botox (onabotulinumtoxinA).

- Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.
- Disclaimer: Every effort has been made to ensure that the information provided by Cerner Multum, Inc. ('Multum') is accurate, up-to-date, and complete, but no guarantee is made to that effect. Drug information contained herein may be time sensitive. Multum information has been compiled for use by healthcare practitioners and consumers in the United States and therefore Multum does not warrant that uses outside of the United States are appropriate, unless specifically indicated otherwise. Multum's drug information does not endorse drugs, diagnose patients or recommend therapy. Multum's drug information is an informational resource designed to assist licensed healthcare practitioners in caring for their patients and/or to serve consumers viewing this service as a supplement to, and not a substitute for, the expertise, skill, knowledge and judgment of healthcare practitioners. The absence of a warning for a given drug or drug combination in no way should be construed to indicate that the drug or drug combination is safe, effective or appropriate for any given patient. Multum does not assume any responsibility for any aspect of healthcare administered with the aid of information Multum provides. The information contained herein is not intended to cover all possible uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the drugs you are taking, check with your doctor, nurse or pharmacist.

Date modified: May 03, 2017
Last reviewed: April 17, 2017