BOTOX®

(botulinum toxin, type A) purified neurotoxin complex

Consumer Medicine Information

The information in this leaflet is ONLY a summary and is not a complete statement about BOTOX® injection. Your doctor has more detailed information relating to you, your medical history and the product and should be consulted so that you will be informed about all aspects of BOTOX® injection as it relates to you.

Please read this leaflet carefully before receiving BOTOX® injection and keep this leaflet handy as you may want to refer to it in the future. If you have any concerns about receiving this medicine, ask your doctor.

CONTENTS

This leaflet answers some common questions about

1. Product description

2. What BOTOX® injection is used for

3. What to be careful of

4. How to use BOTOX® injection

5. Side effects

6. Storage and disposal

7. Further information

All medicines have benefits and risks. Your doctor has weighed the risks of using BOTOX® injection against the benefits expected from using it for you.

1.PRODUCT DESCRIPTION

What is BOTOX® injection?

The injection contains a muscle relaxant obtained from the bacterium Clostridium botulinum.

What is in BOTOX® injection?

Each vial contains either 50 units (U), 100 U or 200 U of Clostridium botulinum toxin type A-haemagglutinin complex as the active ingredient. It also contains human albumin and sodium chloride.

What it looks like

The injection is supplied as a sterile white vacuum-dried powder in a clear glass vial. It is diluted before use with non-preserved, sterile 0.9% w/w sodium chloride injection.

2. WHAT BOTOX® INJECTION IS USED FOR

How BOTOX® injection works

BOTOX® works by temporarily relaxing overactive or spastic (contracting) muscles. BOTOX® can also block signals to the sweat glands thus reducing excessive sweating (hyperhidrosis), and can also block the release of chemicals in the brain associated with the cause of pain (chronic migraine). When injected into the bladder wall, BOTOX® works on the bladder muscle to prevent leakage of urine (urinary incontinence).

It is used to treat medical conditions associated with overactive muscles:

- causing excessive eyelid blinking (blepharospasm) in patients twelve years and over
- of the face (hemifacial spasm and VIIth nerve disorders) in patients twelve years and over

- causing 'lazy eye' or squint (strabismus) in patients twelve years and over
- in the throat, causing a strained, strangled sounding voice or breathy voice with voice loss (spasmodic dysphonia)
- causing the head to be in an unusual posture or pain in the neck associated with twisting of the head (cervical dystonia)
- in children aged two years and older, causing altered and unnatural position or movements in the hand and arm as well as legs, including those muscles that cause abnormal ankle position and walking gait (juvenile cerebral palsy)
- in adults, causing focal spasticity in the shoulders, hands, arms or legs (adult focal spasticity).

BOTOX® is also used:

- to treat overactive bladder in adults with leakage of urine (urinary incontinence), the sudden urge to empty your bladder and needing to go to the toilet more than usual when another drug (called an anticholinergic) did not help. BOTOX® has been shown to markedly reduce leakage of urine and improve the quality of life of patients suffering from leakage of urine due to overactive bladder
- to treat leakage of urine (urinary incontinence) in adults with overactive bladder due to neurologic disease. BOTOX® has been shown to reduce leakage of urine and

improve the quality of life of patients suffering from leakage of urine due to neurogenic bladder

- to treat headaches occurring in adults with chronic migraine
- to treat excessive sweating from the armpit area
- to improve the look of vertical frown lines that appear between the eyebrows, lines around the eyes and on the forehead in adults
- to temporarily improve the appearance of continuous vertical bands connecting the jaw and neck (platysma muscle) seen at maximum contraction in healthy adults.

Availability

The Department of Health has approved BOTOX® injection for the uses listed above. However, your doctor may use this medicine for another purpose. If you want more information, ask your doctor.

3. WHAT TO BE CAREFUL OF

BOTOX® injection must not be used if:

- you are allergic to any of the ingredients listed in section 1 (Product Description)

- you have an infection in the muscles where it would normally be injected
- you have any muscle disorders in other parts of your body, such as myasthenia gravis or Eaton Lambert Syndrome
- you are being treated for leakage of urine and
    - have either a sudden onset of urinary tract infection (UTI) or
    - have a sudden inability to empty your bladder (and are not regularly using a catheter)
    - are not willing and/or able to begin using a catheter, if required
- the container is damaged or shows signs of tampering, or if the product does not look quite right

Tell your doctor if:

- you have any muscle disorders in other parts of your body, including amyotrophic lateral sclerosis, and motor neuropathy
- you are scheduled to have surgery using a general anaesthetic
- you are taking anti-platelets (aspirin-like products) and/or anti-coagulants (blood thinners)

- you have inflammation or severe weakness in the muscles where BOTOX® would be injected
- you have a breathing problem, such as asthma or emphysema
- your child who is being treated with BOTOX® for juvenile cerebral palsy has or has had neurological problems, swallowing problems, lung disease or aspiration pneumonia (serious lung infection)
- you have swallowing problems
- you have bleeding problems
- you have had surgery on your face or in your eye
- you have drooping eyelids
- you have any other change in the way your face normally looks
- you have angle closure glaucoma
- you have problems with your heart or circulation
- you have had seizures
- you are pregnant or have the intention of becoming pregnant
- you are breastfeeding or planning to start breastfeeding
- you are being treated for leakage of urine and

- have chronic urinary tract infection which you take long term antibiotic to treat
- have urinary obstruction. Symptoms and signs include difficulty emptying your bladder and reduced urine flow

- you are being treated for leakage of urine due to overactive bladder and have diabetes

In these circumstances it may not be possible to use BOTOX®. Tell your doctor if you have 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.

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.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and BOTOX® may interfere with each other.

Especially tell your doctor if you:

- have received any other botulinum toxin product in the last four months
- have recently received an antibiotic by injection, such as gentamycin or tobramycin
- take muscle relaxants
- take an allergy or cold medicine
- take a sleep medicine.

4. HOW TO USE BOTOX® INJECTION

BOTOX® injection should only be administered by a doctor familiar with the required technique. It must be dissolved in sterile saline solution immediately before use and should not be used in higher doses or more frequently than recommended.

When treating paediatric patients, for one or more indications, the maximum cumulative BOTOX® dose in a 3-month period should generally not exceed 8 Units/kg body weight or 300 Units, whichever is lower (refer to indication-specific maximum dosing recommendations).

The usual dosage of BOTOX® is as follows:

For leakage of urine due to overactive bladder

Dosage

Your doctor will give multiple injections into the bladder wall via a specific instrument (cystoscope). The total dose is 100 U of BOTOX®. You may be given a local anaesthetic before the injections (your bladder would be filled with anaesthetic solution for a while and then drained). You may also be given a sedative.

Duration of treatment effect

You will usually see an improvement within 2 weeks after the injection.

Typically, the effect lasts 5 – 6 months after the injection.

When the effects start to wear off, you can have the treatment again if needed, but not more often than every 3 months.

For leakage of urine due to bladder problems associated with spinal cord injury or multiple sclerosis

Dosage

Your doctor will give multiple injections into the bladder wall via a specific instrument (cystoscope). The total dose is 200 U

of BOTOX®. You may be given a local or general anaesthetic before the injections. You may also be given a sedative.

Duration of treatment effect

You will usually see an improvement within 2 weeks after the injection.

Typically, the effect lasts 8-10 months after the injection.

When the effects start to wear off, you can have the treatment again if needed, but not more often than every 3 months.

Blepharospasm, Hemifacial Spasm and VIIth Nerve Disorders

The recommended dose is 1.25 U to 2.5 U (0.05 mL to 0.1 mL) for each muscle injected. The initial effect occurs within 3 days, with the maximum muscle relaxation reached within 1-2 weeks, and lasting approximately 3 months. After this, you should return for a repeat dose. The total maximum dose in a 2 month period should not be more than 200 U.

Strabismus

The volume of BOTOX® injected for the treatment of strabismus or squint should be between 0.05 to 0.15 mL per eye muscle. The muscle relaxation effect begins one to two days after the injection and lasts 2 to 6 weeks. You may need to return for a repeat dose if the effect is inadequate or if the

squint recurs. The maximum recommended dose as a single injection for any one muscle is 25 U.

Spasticity in children two years and older

The recommended total dose is up to 8 U/kg injected into the spastic muscles. The maximum total dose is 300 U per treatment session or in a 3 month interval. The initial effect occurs within 2 weeks after injection. The dose is dependent on the size of the spastic muscle and the degree of spasticity. The dose can then be repeated but not more often than every 3 months.

Focal spasticity in Adults

Your doctor will determine the appropriate dose and the number of injection sites based on the number of spastic muscles, the severity of the spasticity and the site and location of the muscles involved. Your doctor may also tailor your dose depending on any muscle weakness that may be present and your response to the injection. Improvement generally occurs within the first 2 weeks after injection, with maximum effect occurring after 4-6 weeks and the effect lasting approximately 3-4 months.

In general, the total maximum dose should not be more than 400 U divided among involved muscles for treating adult upper limb spasticity, and maximum dose of 400 U divided among involved muscles for treating adult lower limb spasticity in any treatment session.

Cervical Dystonia

The recommended dose depends on the type of muscle spasm, the position of the head and neck, whether muscle weakness is present, where pain is felt, your weight and response to the injection. Your doctor will prescribe the proper dose for you. Improvement generally occurs within the first 2 weeks after the injection, with the maximum effect after 6 weeks, and the effect lasting approximately 3-4 months. In general, the total maximum dose in a 2 month period should not be more than 360 U.

Spasmodic Dysphonia

Your doctor will determine the appropriate dose for you at each treatment session. Improvement generally occurs within 2-4 days. The maximum effect is seen within approximately 7 days with the effect lasting approximately 3-4 months.

Chronic Migraine

The recommended dose for treating chronic migraine is 155 U to 195 U administered intramuscularly as 0.1 ml (5 U) injections across 7 specific muscle areas in the head and neck. The dose can then be repeated every 12 weeks, for up to 3 cycles, and then assessment of the need for further treatment should be conducted.

Primary Hyperhidrosis

Recommended dosage is 50 U of BOTOX® (2.0 mL) per armpit, evenly distributed in multiple sites approximately 1-2 cm apart within the armpit area. Injections should be repeated

when the effects from the previous injection wear off but not more often than every 4 months.

Frown Lines

The recommended dose of BOTOX® for the treatment of frown lines is 20 U. This is usually injected into the muscles around your eyebrows in 5 different places. The recommended injection volume per muscle site is 0.1 mL. However, the optimum dose levels and number of injections sites per muscles may vary among patients. Improvement in the severity of the lines generally occurs within one week after the injections and has been shown to last for up to 4 months. This will vary between individual people and may depend on the severity of the frown lines.

Crow's Feet

The recommended dose of BOTOX® injection for the treatment of crow's feet lines is 6-18 U per side. This is usually injected into the muscles around your eyes, where most lines are seen when a smile is forced, in 3 different places. Improvement in the severity of the lines generally occurs within one week after the injections and has been shown to last for up to 4 months.

Forehead Lines

The recommended dose of BOTOX® for the treatment of forehead lines is 8-24 U. This is usually injected into the forehead muscle in 4 different places. Improvement in the

severity of the lines generally occurs within two weeks after the injections and has been shown to last for up to 6 months.

Continuous vertical bands connecting the jaw and neck (platysma muscle) seen at maximum contraction

BOTOX® is injected directly into the muscle of the affected area at each side of the neck.

The usual dose is either 26, 31, or 36 Units. You will be injected with the recommended volume of 0.05 ml (2 Units) of BOTOX® into 4 sites in the upper segment of platysma muscle, below the jawline on each side. In addition, you will be injected with 0.025 ml (1 Unit) of BOTOX® into 5 sites along each vertical neck band, 1 to 2 vertical neck bands per side. Depending on platysma continuous bands severity, the total dose may be 26 Units (1 band/side), 31 Units (1 band one side, 2 bands other side), or 36 Units (2 bands/side). You cannot receive another platysma treatment sooner than 3 months.

Use in pregnancy

Use of BOTOX® when pregnant or breast-feeding is not recommended. Tell your doctor or pharmacist if you become pregnant while being treated with BOTOX®.

Use in children

The safety and effectiveness of BOTOX® has been established in children/adolescents over the age of two years for the treatment of focal spasticity due to juvenile cerebral palsy.

Focal spasticity of the upper and lower limbs in children who have Cerebral Palsy	2 years

Limited information is available on the use of BOTOX® in the following conditions in children/adolescents over the age of 12 years. No recommendation on dosage can be made for these indications.

Persistent muscle spasms in the eyelid and face	12 years
Persistent muscle spasms in neck and shoulder	16 years
Excessive sweating of the armpits	12 years
Persistent muscle spasms in the eye causing 'Lazy eye' or squint	12 years
Persistent muscle spasms in the throat, causing a strained, strangled sounding voice or breathy voice with voice loss	12 years

Things to be careful of

- Tell your doctor as soon as possible if you do not feel well while being treated with BOTOX® injection.
- Be careful to resume activities gradually if you have had little exercise for a long time.
- Be careful driving or operating machinery until you know how BOTOX® affects you.

Urinary incontinence due to overactive bladder

- You will be seen by your doctor approximately 2 weeks after the injection. You will be asked to pass urine and will then have the volume of urine left in your bladder measured using ultrasound. Your doctor will decide if you need to return for the same test during the next 12 weeks. You must contact your doctor if at any time you find it difficult to pass urine because it is possible that you may need to start using a catheter. In order to avoid urinary tract infections, female patients should pass urine after sexual intercourse.
- Please note only a small percentage (12.2%) of patients included in the main clinical trials were male. The improvement seen in male patients following use in BOTOX® is smaller than in female patients and may not be beneficial. No significant reduction in incontinence frequency was seen and a majority of men in the clinical trials felt that their condition was unchanged or worsened after receiving BOTOX®. There are also side effects such

as urinary tract infection and inability to empty your bladder (urinary retention) associated with BOTOX® treatment. The decision to receive treatment with BOTOX® should be discussed with your doctor.

Urinary incontinence due to neurogenic bladder

- You will be seen by your doctor approximately 2 weeks after the injection, if you were not using a catheter before the injection. You will be asked to pass urine and will then have the volume of urine left in your bladder measured using ultrasound. Your doctor will decide if you need to return for the same test during the next 12 weeks. You must contact your doctor if at any time you find it difficult to pass urine because it is possible that you may need to start using a catheter. In order to avoid urinary tract infections, female patients should pass urine after sexual intercourse.

Overdose

Telephone your doctor or go to casualty at your nearest hospital immediately if you think that you or anyone else may have swallowed or accidentally injected BOTOX® injection, even if there are no signs of discomfort or poisoning. You may need to be watched for several days for signs of muscle weakness or loss of muscle movement.

Tell your doctor if you feel any general weakness, local muscle weakness, difficulty in breathing or swallowing in the

weeks following your injection. There is an anti-toxin to the toxin in BOTOX®, but it is only likely to be effective if injected within 30 minutes after the BOTOX® injection. If you have questions or concerns or are not sure about something, please consult your doctor or pharmacist.

5. SIDE EFFECTS

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Some patients may experience unwanted effects with BOTOX® treatment, and may need further medical treatment. Ask your doctor to answer any questions you may have.

If while undergoing treatment with BOTOX® injection you experience any side-effects or symptoms which may be due to this medication (whether or not it is mentioned below) please inform your Doctor as early as possible.

This product contains albumin, an extract of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

Things which may occur

General

Pain, tenderness, inflammation, tingling or numbness, swelling (including swelling of the eyelid following injection), dry mouth, redness of the skin, infection, bleeding and/or bruising at the site of injection, generally feeling unwell and weakness. The following symptoms have been reported on rare occasions: changes in the way the heart beats, chest pain, skin rash and allergic reaction (symptoms: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin).

In some cases, the effect of botulinum toxin may be observed beyond the site of injection and the following symptoms may occur:

- loss of strength and muscle weakness
- drooping of the upper eyelid
- double or blurred vision
- trouble speaking or saying words clearly
- constipation

- aspiration pneumonia (serious lung infection)
- trouble swallowing or breathing, which can be life-threatening.

These symptoms can happen hours to weeks after injection and are more likely to occur in patients treated with high doses or who have underlying conditions that would predispose them to these symptoms.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience any of the above symptoms.

Injections in the bladder wall for leakage of urine due to overactive bladder

Very common side effects: urinary tract infection, painful urination after the injection*.

Common side effects: bacteria in the urine, inability to empty your bladder (urinary retention), incomplete emptying of the bladder, frequent daytime urination, blood in the urine after the injection**.

*** This side effect may also be related to the injection procedure.**

****This side effect is only related to the injection procedure.**

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Injections in the bladder wall for leakage of urine due to bladder problems associated with spinal cord injury or multiple sclerosis

Very common side effects: urinary tract infection, inability to empty your bladder (urinary retention).

Common side effects: difficulty in sleeping, constipation, muscle weakness, muscle spasm, bulge in the bladder wall, tiredness, problems with walking, fall.

Common side effects related to the injection procedure: blood in the urine after the injection, painful urination after the injection, possible uncontrolled reflex reaction of your body (e.g. profuse sweating, throbbing headache or increase in pulse rate) around the time of the injection.

Blepharospasm, Hemifacial Spasm or VIIth Nerve Disorders

Drooping of the eyelids, irritation or tearing, dry eye, not being able to close the eye, sensitivity to light, dizziness and tiredness. Less common side effects include: inward or outward turning of the eye, inflammation of the eye, double vision, and swelling of the eyelid skin lasting several days.

Strabismus

Drooping of the eyelids, vertical turning of the eye, double vision, bleeding beneath the eye lids and at the front of the eye. Less common side effects include: bleeding behind the eye ball, piercing of the sclera (the tough skin covering part of the eye bulb), dilation of the pupil, loss of awareness of space and past pointing (the inability to place a finger on another part of the body accurately), headache, inability to focus, dizziness, discomfort/irritation of the eye, increased pressure in the eye.

Spasticity in children two years and older

Falling, clumsiness, localised, and/or generalised muscle weakness, localised pain, problems with walking, flu, viral infections, ear infection and pain, bruising and discomfort at

the injection site. Less common side effects include: leg cramps, fever, knee or ankle pain, increased frequency of passing urine, joint dislocation and muscle spasms. Seizures, pneumonia, vomiting, bruising, rash, abnormal skin sensations (e.g. tingling or numbness), feeling drowsy or sleepy, generally feeling unwell and running nose were also reported.

Focal spasticity in adults

Most side effects that have been reported in patients being treated for focal spasticity were mild to moderate and got better without needing medical attention. Side effects reported include: nausea, weakness of muscles, pain in extremities such as hands and feet, tiredness and swelling of the extremities such as hands and feet.

Cervical Dystonia

Soreness or bruising where the injection was given, difficulty in swallowing, neck pain, headache, weakness of the neck, dizziness, feeling drowsy or sleepy, dry mouth, nausea, flu-like illness, upper respiratory tract infection, increased muscle tension, muscle stiffness and decreased skin sensation. Less common side effects include: general weakness, fever, shortness of breath, double vision and drooping of the eyelid. Side effects, if they occur, tend to appear in the first week after injection.

However, in rare instances, patients may have serious difficulty in breathing and swallowing that could occur within hours of injection and may persist for weeks after injection and may develop into a more serious condition. Make sure you tell your doctor immediately if you experience any difficulty in swallowing.

Spasmodic Dysphonia

Breathiness, difficulty in swallowing, inhalation of fluid or food particles from the stomach, narrowed air passages causing a harsh sound in breathing and pain were among the more common side effects reported in clinical trials.

Chronic Migraine

Loss of movement on the face, drooping of the eyelids, skin rash, itching, pain at the injection site, neck pain, muscle pain, tenderness or weakness, muscle spasms or tightness. Less common side effects include: pain of skin, pain of jaw and difficulty in swallowing. Mephisto sign (quizzical or Spock's eyebrow, when the outer end of the eyebrow is located above the inner end) has been reported in post-marketing experience.

Headache, including worsening migraine, has been also reported, usually occurring within the first month after

treatment; however, these reactions did not always reoccur with following treatments and the overall incidence decreased with repeated treatments.

Primary hyperhidrosis

Increase in sweating in other areas of the body, hot flushes and pain at the injection site.

Frown Lines

Drooping of the eyelids, headache, face pain, redness, swelling at the injection site, bruising, skin tightness, muscle weakness, numbness or a feeling of pins and needles or nausea were among the more common effects reported in clinical trials. Inability to completely close the eyelid and Mephisto sign (quizzical or Spock's eyebrow, when the outer end of the eyebrow is located above the inner end) have been reported in post-marketing experience.

Crow's Feet

Bruising at the injection site, headache, flu-like symptoms and inability to completely close the eyelid.

Forehead Lines

Headache, bruising, drooping of the eyebrows, eyelid swelling, aching/itching forehead, nausea, feeling of tension and flu-like symptoms.

Injections for the temporary improvement in continuous vertical bands connecting the jaw and neck (platysma muscle) seen at maximum contraction

Uncommon:

may affect up to 1 in 100 people

- difficulty swallowing
- weakness in the lower part of the face.

6. STORAGE AND DISPOSAL

- BOTOX® injection should not be used after the date marked on the label (expiry date).
- KEEP ALL MEDICINES WHERE YOUNG CHILDREN CANNOT REACH THEM.
- BOTOX® injection should be stored in the refrigerator. The injection should be given within 24 hours after being reconstituted and stored in a refrigerator during this time. The injection should be clear, colourless and free from

particles. Each vial is intended for use by a single individual patient.

7. FURTHER INFORMATION

If you have any further questions on your BOTOX® treatment or are unsure of the information, please see your doctor, who will be able to assist you.

Supplier

AbbVie Pty Ltd

241 O'Riordan Street

Mascot NSW 2020

Australia

Australian Registration Number

BOTOX® 50 U - AUST R 195530

BOTOX® 100 U - AUST R 67311

BOTOX® 200 U - AUST R 172264

Date of preparation

June 2025