

# BOTOX®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor.

### 1. Why am I using BOTOX®?

BOTOX® injection contains the active ingredient botulinum toxin type A. BOTOX® injection works by temporarily relaxing overactive or spastic (contracting) muscles and hence can be used to treat many conditions associated with the same.

For more information, see Section [1. Why am I using BOTOX®?](#) in the full CMI.

### 2. What should I know before I use BOTOX®?

Check the list of ingredients at the end of the CMI. Do not use BOTOX® if you have ever had an allergic reaction to any of them.

**Talk to your doctor before you use this medicine. Ensure they are aware if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use BOTOX®?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines and BOTOX® may interfere with each other and affect how they work. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How is BOTOX® used?**

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.

More instructions can be found in Section [4. How is BOTOX® used?](#) in the full CMI.

### **5. What should I know while using BOTOX®?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, pharmacist or other health care professional you visit that you are using BOTOX® injection.</li><li>• Follow all directions given to you by your</li></ul>
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	<p>doctor before, during and after you have your BOTOX® injection.</p> <ul style="list-style-type: none"> <li>• Be careful to resume activities gradually if you have had little exercise for a long time.</li> <li>• Tell your doctor as soon as possible if you do not feel well while being treated with BOTOX® injection.</li> <li>• In order to avoid urinary tract infections, female patients should pass urine after sexual intercourse.</li> </ul>
<b>BOTOX® injection must not be used if:</b>	<ul style="list-style-type: none"> <li>• you are allergic to any of the ingredients listed in section 7 (Product Details)</li> <li>• you have an infection in the muscles where it would normally be injected</li> <li>• you have any muscle disorders in other parts of your body, such as myasthenia gravis or Eaton Lambert Syndrome</li> </ul>

	<ul style="list-style-type: none"> <li>• you are being treated for leakage of urine and 1) have either a sudden onset of urinary tract infection (UTI) or 2) sudden inability to empty your bladder (and are not regularly using a catheter) or 3) not willing and/or able to begin using a catheter, if required.</li> </ul>
<b>Driving or using machines</b>	Be careful driving or operating machinery until you know how BOTOX® injection affects you.
<b>Looking after your medicine</b>	BOTOX® is an injectable medicine which will only be provided to you by your healthcare practitioner in a clinic setting.

For more information, see Section [5. What should I know while using BOTOX®?](#) in the full CMI.

## 6. Are there any side effects?

The most serious side effects requiring urgent medical attention include: loss of strength/muscle weakness, drooping eyelid, double or blurred vision, trouble speaking, aspiration pneumonia, trouble swallowing or

breathing, changes to heart beats, chest pain, skin rash, allergic reaction (symptoms include shortness of breath, wheezing swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin); and in children: pneumonia, seizures.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

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.

## **BOTOX®** (boh-tox)

**Active ingredient:** [*botulinum toxin type A*] (bot-yu-lyn-um)

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### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using BOTOX®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BOTOX®.**

#### **Where to find information in this leaflet:**

- [1. Why am I using BOTOX®?](#)
- [2. What should I know before I use BOTOX®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is BOTOX® used?](#)
- [5. What should I know while using BOTOX®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

# 1. Why am I using BOTOX®?

**BOTOX® injection contains the active ingredient botulinum toxin type A**, a muscle relaxant obtained from the bacterium *Clostridium botulinum*.

BOTOX® injection 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).

**BOTOX® 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 an 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 medicine (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
- 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. associated with neurologic disease
- treat headaches occurring in adults with chronic migraine
- treat excessive sweating from the armpits
- improve the look of vertical frown lines that appear between the eyebrows, lines around the eyes and on the forehead in adults
- temporarily improve the appearance of continuous vertical bands connecting the jaw and neck (platysma muscle) seen at maximum contraction in healthy adults.



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.

## **2. What should I know before I use BOTOX®?**

### **Warnings**

#### **Do not use BOTOX® if:**

- you are allergic to botulinum toxin type A or any of the ingredients listed at the end of this leaflet
- 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) or are not willing and/or able to use a catheter, if required
- the container is damaged or shows signs of tampering, or if the product does not look quite right.

## **Check with your doctor if:**

- you have any muscle disorders in other parts of your body, including motor neuron disease such as amyotrophic lateral sclerosis and motor neuropathy
- you are scheduled to have surgery where a general anaesthetic will be used
- you are taking medicines used to thin the blood (anti-coagulants) and/or prevent blood clots (aspirin-like products)
- 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 (a 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 being treated for leakage of urine and have a chronic urinary tract infection for which you take long term antibiotics to treat
- you are being treated for leakage of urine and have a urinary obstruction. Symptoms and signs include difficulty emptying your bladder and reduced urine flow
- you are being treated for leakage of urine due to an overactive bladder and have diabetes
- you are pregnant or have the intention of becoming pregnant.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

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®.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

## **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.

- Limited information is available on the use of BOTOX® in the following conditions in children/adolescents listed below. No recommendation on dosage can be made for these indications.
- **over the age of 12 years:**
  - persistent muscle spasms in the eyelid and face
  - persistent muscle spasm in the eye causing a "lazy eye" or squint
  - excessive sweating of the armpits
  - persistent muscle spasms in the throat, causing a strained, strangled sounding voice or breathy voice with voice loss.
- **over the age of 16 years:**
  - persistent muscle spasms in neck and shoulder.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with BOTOX® and may cause serious side effects. Especially tell your doctor if you:**

- have received any other botulinum toxin product injected 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BOTOX®.**

### **4. How is BOTOX® used?**

#### **How much to use**

- BOTOX® product 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).

## **When to use BOTOX®**

- You may receive follow-up BOTOX® injection(s) if the effect begins to wear off, depending on the condition for which you are being treated.

## **How to use BOTOX®**

- BOTOX® injection should only be administered by a doctor familiar with the required technique.

## **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.

## **If you use too much BOTOX®**

**If you think you or anyone else may have swallowed or accidentally injected BOTOX®, immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this 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.** There is an anti-toxin to the toxin in BOTOX® but it is only likely to be effective if injected within 30 minutes after a BOTOX® injection.

**Tell your doctor if you feel any general weakness, local muscle weakness, difficulty in breathing or swallowing in the weeks following your injection.**

## **5. What should I know while using BOTOX®?**

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 the transmission of Creutzfeldt-Jakob disease (CJD) is considered extremely remote.

No cases of transmission of viral diseases or CJD have ever been identified for albumin.

## **Things you should do**

- Be careful to resume activities gradually if you have had little exercise for a long time.
- Tell your doctor as soon as possible if you do not feel well while being treated with BOTOX® injection.
- Remind any doctor, dentist, pharmacist, or other health care professional you visit that you are using BOTOX®.
- In order to avoid urinary tract infections, female patients should pass urine after sexual intercourse.
- If you are being treated for 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.

- If you are being treated for 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.

### **Call your doctor straight away if you:**

- **Feel any general weakness, local muscle weakness, difficulty in breathing or swallowing in the weeks following your injection**

- **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)**

## **Driving or using machines**

Be careful driving or operating machinery until you know how BOTOX® affects you.

## **Looking after your medicine**

BOTOX® is an injectable medicine which will only be provided to you by your healthcare practitioner in a clinic setting.

## **Getting rid of any unwanted medicine**

Any unused medicine left in a vial will be thrown away by your doctor or nurse.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Note that some side effects can occur hours, and up to weeks after a BOTOX® injection.

**See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.**

### **Very serious side effects**

<b>Very serious side effects</b>	<b>What to do</b>
<p><b>Applicable to any condition being treated:</b></p> <p>In some cases, the effect of botulinum toxin may be observed beyond the site of injection and the following symptoms may occur:</p> <ul style="list-style-type: none"><li>• loss of strength and muscle weakness</li><li>• drooping of the upper eyelid</li><li>• double or blurred vision</li><li>• trouble speaking or saying words clearly</li><li>• aspiration pneumonia (serious lung infection)</li><li>• trouble swallowing or breathing, which can be life-threatening</li></ul>	<p><b>Go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b></p>



Very serious side effects	What to do
<p>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.</p> <p>The following symptoms have been reported on rare occasions:</p> <ul style="list-style-type: none"> <li>• changes in the way the heart beats, chest pain</li> <li>• skin rash</li> <li>• symptoms of an allergic reaction, including 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).</li> </ul> <p><b>Spasticity in children two years and older:</b></p> <p>Less common side effects include:</p>	

<b>Very serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• severe infection on the chest (pneumonia)</li> <li>• seizures (fits)</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Applicable to any condition being treated:</b></p> <ul style="list-style-type: none"> <li>• infection</li> <li>• feeling generally unwell</li> <li>• weakness</li> </ul> <p><b>Injections in the bladder wall for leakage of urine due to overactive bladder:</b></p> <ul style="list-style-type: none"> <li>• urinary tract infection</li> <li>• unable to completely empty your bladder (urine retention)</li> </ul> <p><b>Injections in the bladder wall for leakage of urine due to bladder problems associated with spinal cord injury or multiple sclerosis:</b></p>	<p><b>Call your doctor straight away, if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<p>Very common side effects</p> <ul style="list-style-type: none"> <li>• urinary tract infection</li> <li>• inability to empty your bladder (urinary retention)</li> </ul> <p>Common side effects</p> <ul style="list-style-type: none"> <li>• problems with walking, falling over</li> </ul> <p>Common side effects related to the injection procedure</p> <ul style="list-style-type: none"> <li>• incomplete emptying of the bladder</li> <li>• possible uncontrolled reflex reaction of your body (e.g. profuse sweating, throbbing headache or increase in pulse rate) around the time of the injection.</li> </ul> <p><b>Blepharospasm, Hemifacial Spasm or VIIth Nerve Disorders:</b></p> <ul style="list-style-type: none"> <li>• inward or outward turning of the eye</li> <li>• inflammation of the eye</li> </ul>	

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• swelling of the eyelid skin lasting several days</li> </ul> <p><b>Strabismus</b></p> <ul style="list-style-type: none"> <li>• vertical turning of the eye</li> <li>• bleeding beneath the eye lids and at the front of the eye</li> <li>• bleeding behind the eye ball</li> <li>• piercing of the sclera (tough skin covering part of the eye bulb)</li> <li>• dilation of the pupil</li> <li>• loss of awareness of space and past pointing (inability to place a finger on another part of the body accurately)</li> <li>• inability to focus</li> <li>• increased pressure in the eye</li> </ul> <p><b>Spasticity in children two years and older:</b></p> <ul style="list-style-type: none"> <li>• clumsiness</li> <li>• falling</li> </ul>	

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• localised, and/or generalised muscle weakness</li> <li>• localised pain</li> <li>• problems with walking</li> <li>• bruising and discomfort at the injection site</li> </ul> <p>Less common side effects include:</p> <ul style="list-style-type: none"> <li>• leg cramps</li> <li>• fever</li> <li>• knee or ankle pain</li> <li>• increased frequency of passing urine</li> <li>• bruising</li> <li>• generally feeling unwell</li> <li>• running nose</li> <li>• abnormal skin sensations (tingling or numbness)</li> <li>• flu</li> <li>• viral infections</li> <li>• ear pain or infection</li> <li>• muscle spasms</li> <li>• vomiting</li> <li>• feeling sleepy or drowsy</li> <li>• joint dislocation</li> </ul>	

Serious side effects	What to do
<p><b>Cervical Dystonia:</b></p> <ul style="list-style-type: none"> <li>• difficulty in swallowing</li> <li>• upper respiratory tract infection</li> <li>• fever</li> <li>• shortness of breath</li> </ul> <p><b>Spasmodic Dysphonia:</b></p> <ul style="list-style-type: none"> <li>• breathiness</li> <li>• inhalation of fluid or food particles from the stomach</li> <li>• narrowed air passages causing a harsh breathing sound</li> <li>• pain</li> </ul> <p><b>Chronic Migraine:</b></p> <ul style="list-style-type: none"> <li>• difficulty in swallowing</li> </ul> <p><b>Continuous vertical bands connecting the jaw and neck (platysma muscle)</b></p> <ul style="list-style-type: none"> <li>• difficulty swallowing</li> </ul>	

## Less serious side effects

Less serious side effects	What to do
<p><b>Applicable to any condition being treated:</b></p> <ul style="list-style-type: none"> <li>• Pain, tenderness</li> <li>• inflammation</li> <li>• tingling or numbness</li> <li>• swelling (including swelling of the eyelid following injection)</li> <li>• dry mouth</li> <li>• redness of the skin</li> <li>• bleeding and/or bruising at the site of injection</li> <li>• constipation</li> </ul> <p><b>Injections in the bladder wall for leakage of urine due to overactive bladder</b></p> <p>Common side effects include:</p> <ul style="list-style-type: none"> <li>• bacteria in the urine</li> <li>• pain when passing urine (may be related to the injection procedure)</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• frequent daytime urination</li> <li>• blood in the urine (only related to injection procedure)</li> </ul> <p><b>Injections in the bladder wall for leakage of urine due to bladder problems associated with spinal cord injury or multiple sclerosis</b></p> <ul style="list-style-type: none"> <li>• difficulty sleeping, tiredness</li> <li>• muscle spasm</li> <li>• blood in the urine (only related to the injection procedure)</li> <li>• painful urination (only related to the injection procedure)</li> <li>• constipation</li> <li>• muscle weakness</li> <li>• bulge in the bladder wall</li> </ul> <p><b>Blepharospasm, Hemifacial Spasm or VIIth Nerve Disorders:</b></p> <ul style="list-style-type: none"> <li>• eye irritation or tearing</li> <li>• dry eye</li> </ul>	



Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• not being able to close the eye</li> <li>• sensitivity to light</li> <li>• dizziness</li> <li>• tiredness</li> </ul> <p><b>Strabismus</b></p> <ul style="list-style-type: none"> <li>• headache</li> <li>• dizziness</li> <li>• discomfort/irritation of the eye</li> </ul> <p><b>Focal spasticity in adults:</b></p> <p>Most side effects reported in patients being treated for focal spasticity were mild to moderate and got better without needing medical attention</p> <ul style="list-style-type: none"> <li>• nausea</li> <li>• weakness of muscles</li> <li>• pain in extremities such as hands and feet</li> <li>• tiredness and swelling of the extremities such as hands and feet</li> </ul> <p><b>Cervical Dystonia:</b></p>	

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• soreness or bruising at the site of injection</li> <li>• neck pain</li> <li>• weakness of the neck</li> <li>• headache</li> <li>• feeling drowsy or sleepy</li> <li>• dry mouth</li> <li>• nausea</li> <li>• flu-like symptoms</li> <li>• increased muscle tension, muscle stiffness</li> <li>• decreased skin sensation</li> <li>• dizziness</li> </ul> <p>Side effects if they occur tend to appear after the first week of injection.</p> <p><b>Chronic Migraine:</b></p> <ul style="list-style-type: none"> <li>• loss of movement in the face</li> <li>• drooping of the eyelids</li> <li>• skin rash and itching</li> <li>• pain at the injection site</li> <li>• neck pain</li> <li>• muscle pain, tenderness or weakness</li> </ul>	

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• muscle spasms or tightness</li> <li>• quizzical or Spock's eyebrow, when the outer end of the eyebrow is located above the inner end (Mephisto sign)</li> <li>• headache, including worsening of migraine, has been 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</li> </ul> <p>Less common side effects:</p> <ul style="list-style-type: none"> <li>• pain of skin</li> <li>• pain of jaw</li> </ul> <p><b>Primary hyperhidrosis:</b></p> <ul style="list-style-type: none"> <li>• increased sweating in other areas of the body</li> <li>• hot flushes</li> <li>• pain at the site of injection</li> </ul>	

Less serious side effects	What to do
<p><b>Frown lines:</b></p> <ul style="list-style-type: none"> <li>• drooping of the eyelids</li> <li>• headache</li> <li>• face pain</li> <li>• redness, swelling at the injection site</li> <li>• bruising</li> <li>• skin tightness</li> <li>• muscle weakness</li> <li>• numbness or a feeling of pins and needles</li> <li>• nausea</li> <li>• inability to completely close the eyelid</li> <li>• quizzical or Spock's eyebrow, when the outer end of the eyebrow is located above the inner end (Mephisto sign)</li> </ul> <p><b>Crow's feet:</b></p> <ul style="list-style-type: none"> <li>• bruising at the site of injection</li> <li>• headache</li> <li>• flu-like symptoms</li> <li>• inability to completely close the eyelid</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>Forehead lines:</b></p> <ul style="list-style-type: none"> <li>• headache</li> <li>• bruising</li> <li>• drooping of the eyebrows</li> <li>• eyelid swelling</li> <li>• aching/itching forehead</li> <li>• nausea</li> <li>• feeling of tension</li> <li>• flu-like symptoms</li> </ul> <p><b>Continuous vertical bands connecting the jaw and neck (platysma muscle)</b></p> <ul style="list-style-type: none"> <li>• weakness in the lower part of the face</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is only available with a doctor's prescription.

### What BOTOX® injection contains

<b>Active ingredient (main ingredient)</b>	Botulinum toxin type A
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• albumin</li><li>• sodium chloride</li></ul>

**Do not use this medicine if you are allergic to any of these ingredients.**

Your doctor or nurse will store BOTOX® in the fridge (at 2°C to 8°C.)

Keep all medicines where young children cannot reach them.

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.

This medicine should not be used after the expiry date.

## **What BOTOX® looks like**

BOTOX® 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. It is supplied in three strengths:

BOTOX® 50 U (Aust R 195530)

BOTOX® 100 U (Aust R 67311)

BOTOX® 200 U (Aust R 172264)

(Not all presentations may be available)

## **Who distributes BOTOX®?**

BOTOX® is distributed in Australia by:

AbbVie Pty Ltd

Mascot NSW 2020

Australia

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