CONSUMER MEDICINE INFORMATION

BOTOX® (botulinum toxin, type A) purified neurotoxin complex

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.

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This leaflet answers some common questions about

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 100 units (U) of *Clostridium botulinum* toxin type A-haemagglutin 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 sterile 0.9% 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).

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)
- causing 'lazy eye' or squint (strabismus) in children and adults
- 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 hands, arms or legs (adult focal spasticity).

BOTOX® is also used:
- 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.

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 above
- you have an infection in the muscles where it would normally be injected
- you have any muscle disorders in other parts of your body, including myasthenia gravis, Eaton Lambert Syndrome or amyotrophic lateral sclerosis
- 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 myasthenia gravis, Eaton Lambert Syndrome or amyotrophic lateral sclerosis
- you are taking or are likely to take antibiotics, especially aminoglycoside antibiotics
- you are scheduled to have surgery using a general anaesthetic
- you have inflammation or severe weakness in the muscles where BOTOX® would be injected
- you are pregnant or have the intention of becoming pregnant
- you are breast feeding or planning to start breast feeding
- you have ever had facial surgery
- you have angle closure glaucoma
- you have problems with your heart or circulation
- you are taking medicines that may interfere with muscle function
- you have had seizures

In these circumstances it may not be possible to use BOTOX®.

Tell your doctor if you experience any difficulties in swallowing food while on BOTOX®, as it could be related to the dosage. Difficulty in swallowing food, ranging from very mild to severe, can persist for 2-3 weeks after injection, or longer.

Tell your doctor if you are taking other medicines, including any you have bought at your pharmacy, supermarket or health food shop.

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.

The usual dosage of BOTOX® is as follows:

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 two 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 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 4-8 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.

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.

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.

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
Use in children below the age of 12 has not been established for blepharospasm, VIIth nerve disorders, cervical dystonia, hyperhidrosis, spasmodic dysphonia or frown lines.

Use in children two years or older is only recommended for focal spasticity (e.g. juvenile cerebral palsy, spasticity of the arm, hip).

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.

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, or local muscle weakness 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 and/or bruising at the site of injection. Malaise (generally feeling unwell) lasting up to six weeks after injection with BOTOX® 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.

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 commonly, 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 commonly, 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, leg pain, weakness of the leg, localised and generalised muscle weakness. Less commonly, leg cramps, fever and knee or ankle pain, increased frequency of passing urine, joint dislocation and muscle spasms.

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: pain in the affected limb, changes in ease of movement of the muscle, increased sensitivity to touch or pain and headache. Less common side effects include: fever, flu syndrome, weakness or a loss of energy, joint pain, skin problems, nausea, 'pins & needles', itching and lack of coordination.

Cervical Dystonia
Soreness or bruising where the injection was given, difficulty in swallowing, weakness of the neck, and less commonly, general weakness, malaise and nausea. Side effects, if they occur, tend to appear in the first week after injection, and last about two weeks.

However, in rare instances, patients may have difficulty in swallowing that could persist for longer than two weeks **after injection** and may develop into a more serious condition. Make sure you tell your doctor 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.

Primary hyperhidrosis
Increase in sweating in other areas of the body, headaches 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.

Crow's Feet
Bruising at the injection site, headache and flu-like symptoms.

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

6. STORAGE AND DISPOSAL

- BOTOX® should not be used after the date marked on the label (expiry date).
- KEEP ALL MEDICINES WHERE YOUNG CHILDREN CANNOT REACH THEM.
- BOTOX® 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.

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