PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

BOTOX® vacuum-dried injection

Botulinum toxin type A

Read all of this leaflet carefully before you are given BOTOX®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

BOTOX® is not for self medication and must be administered only by a medical practitioner and who is qualified for its use.

What is in this leaflet

1. What BOTOX® is and what it is used for
2. What you need to know before you are given BOTOX®
3. How to receive BOTOX®
4. Possible side effects
5. How to store BOTOX®
6. Contents of the pack and other information

1. What BOTOX® is and what it is used for

BOTOX® is a muscle relaxant used to treat a number of conditions within the body. It contains the active substance Botulinum toxin type A and is injected into either the muscles, the bladder

wall or deep into the skin. It works by partially blocking the nerve impulses to any muscles that have been injected and reduces excessive contractions of these muscles.

- BOTOX® can be injected directly into the muscles, and can be used to control the following conditions:
  - persistent muscle spasms in the upper and lower limbs in children aged two years or older;
  - In adults:
    - Persistent muscle spasms in the upper and lower limbs,
    - Persistent muscle spasms in the eyelid and face;
    - Persistent muscle spasms in the neck and shoulders.
- BOTOX® is used to reduce the symptoms of chronic migraine in adults who have had headaches on 15 or more days each month of which at least 8 days are with migraine and who have not responded well to other preventative migraine medications.

  Chronic migraine is a disease affecting the nervous system. Patients usually suffer from head pain which is often accompanied by excessive sensitivity to light, loud sounds or smells/odours, as well as nausea and/or vomiting. These headaches occur on 15 or more days each month.
- When injected into the bladder wall, BOTOX® works on the bladder muscle to reduce leakage of urine (urinary incontinence) and control the following conditions in adults:
  - Overactive bladder in females with leakage of urine, 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;
  - Leakage of urine due to bladder problems associated with spinal cord injury or multiple sclerosis.
- In adults, BOTOX® can be injected deep into the skin and can work on sweat glands to reduce excessive sweating of the armpits, which affects the activities of daily living when

other local treatments do not help.

- In adults, BOTOX® is used temporarily for the temporary improvement in the appearance of:
  - Vertical lines between the eyebrows seen at maximum frown in adults;
  - Fan-shaped lines from the corner of the eyes (crow's feet lines) seen at maximum smile;
  - Forehead lines seen at maximum raised eyebrows.
- In adults, BOTOX® is used to improve the appearance of vertical neck bands connecting the jaw and neck (platysma prominence).

2. What you need to know before you are given BOTOX®

You should not be given BOTOX®:

- If you are hypersensitive (allergic) to botulinum toxin type A or any of the other ingredients of BOTOX®;
- If you have an infection at the proposed site of injection;
- If you have significant weakness or wasting of the muscles which your doctor plans to inject;
- If you have any muscle disorders in other parts of your body or chronic disease affecting your muscles, such as myasthenia gravis, or Eaton Lambert Syndrome;
- If you suffer from certain diseases affecting your nervous system (such as amyotrophic lateral sclerosis or motor neuropathy);
- If you are being treated for leakage of urine and have either a urinary tract infection or a sudden inability to empty your bladder (and are not regularly using a catheter);
- If you are being treated for leakage of urine and are not willing to begin using a catheter if required.

Warnings and precautions

Before being given BOTOX®, tell your doctor:

- **If you have ever had problems with swallowing of food or liquid accidentally going**

into your lungs, especially if you will be treated for persistent muscle spasms in the neck and shoulder(s);

- If you are over 65 years of age and have other serious illness;
- If you have had any problems with injections (such as fainting) in the past;
- If you have inflammation in the muscles or skin area where your doctor plans to inject;
- If you have significant weakness or wasting of the muscles which your doctor plans to inject;
- If you suffer from any other muscle problems or chronic diseases affecting your muscles (such as myasthenia gravis or Eaton Lambert Syndrome);
- If you suffer from certain diseases affecting your nervous system (such as amyotrophic lateral sclerosis or motor neuropathy);
- If you suffer from cardiovascular disease (disease of the heart or blood vessels);
- If you suffer or have suffered from seizures;
- If you have an eye disease called glaucoma (high pressure in the eye) or were told you are at risk for developing glaucoma;
- If you have had any surgery or injury that may have in some way changed the muscle to be injected;
- If you are about to be treated for overactive bladder with leakage of urine and you are a male with signs and symptoms of urinary obstruction, such as difficulty in passing urine or a weak or interrupted stream.

The safety and effectiveness of BOTOX® have not been established in children or adolescents under the following ages:

Persistent muscle spasms in children	2 years
Persistent muscle spasms of the eyelid, face	12 years
Neck and shoulder	16 years
Chronic migraine	18 years

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Leakage of urine	18 years
Excessive sweating of the armpits	18 years
Vertical lines between the eyebrows, crow's feet lines and forehead lines	18 years
Vertical neck bands connecting the jaw and neck	18 years

With the exception of overactive bladder, clinical studies of BOTOX® did not identify differences in responses between the elderly and younger patients.

After you have been given BOTOX®

You or your caregiver should contact your doctor and seek medical attention immediately if you experience any of the following:

- **Difficulty in breathing, swallowing, or speaking;**
- **Hives, swelling** including swelling of the face or throat, **wheezing**, feeling **faint** and **shortness of breath** (possible symptoms of severe allergic reaction).

It is possible for the procedure to result in infection, pain, swelling, burning and stinging, increased sensitivity, tenderness, redness, and/or bleeding/bruising at the site of injection.

Side effects, possibly related to the spread of toxin away from the injection site, may occur with BOTOX® (e.g. muscle weakness, difficulty swallowing or unwanted food or liquid in the airways). This is a particular risk for patients with an underlying illness that makes them susceptible to these symptoms.

If you are given BOTOX® too often or the dose is too high, you may experience muscle weakness and side effects related to the spread of toxin or your body may start producing some antibodies, which can reduce the effect of BOTOX®.

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If you have not done much exercise for a long time before receiving BOTOX® treatment, then after your injections you should start any activity gradually.

It is unlikely that BOTOX® will improve the range of motion of joints where the surrounding muscle has lost its ability to stretch.

When BOTOX® is used in the treatment of adults with lower limb spasticity, it should only be used if it is expected to result in improvement in function (e.g. walking) or symptoms (e.g. spasms or pain) or to help with patient care. Furthermore, for patients who may be more likely to fall, your doctor will judge if this treatment is suitable.

When BOTOX® is used in the treatment of persistent muscle spasms in the eyelid, it could make your eyes blink less often, which may harm the surface of your eyes. In order to prevent this, you may need treatment with eye drops, ointments, soft contact lenses or even protective covering which closes the eye. Your doctor will tell you if this is required.

When BOTOX® is used to control the leakage of urine, your doctor will give you antibiotics before and after the treatment to help prevent urinary tract infection. You will be seen by your doctor approximately two 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 are unable to pass urine because it is possible that you may need to start using a catheter.

Other medicines and BOTOX®

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if:

- You are using any antibiotics (used to treat infections) or muscle relaxants. Some of these medicines may increase the effect of BOTOX®;
- You have recently been injected with a medicine containing a botulinum toxin (the active substance of BOTOX®), as this may increase the effect of BOTOX® too much;
- You are using any anti-platelet (asprin-like products) and/or anti-coagulants (blood thinners).

Pregnancy and breast-feeding

The use of BOTOX® is not recommended during pregnancy and in women of childbearing potential not using contraception. BOTOX® is not recommended in breast-feeding women.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care professional for advice before receiving BOTOX®.

Driving and using machines

BOTOX® may cause dizziness, sleepiness, tiredness or problems with your vision. If you experience any of these effects, do not drive or use any machines. If you are not sure, ask your doctor for advice.

BOTOX® contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, i.e. essentially “sodium free”.

Important information about some of the ingredients of BOTOX®

BOTOX® contains human albumin which comes from human blood. There is a possibility of passing on infections. To reduce this risk, blood donors are chosen very carefully. Furthermore,

BOTOX® is made in a way that should remove or destroy viruses.

3. How to receive BOTOX®

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself BOTOX®. It will be given to you by a person who is qualified to do so. BOTOX® must only be injected by a medical doctor with specific skills on how to use the medicine.

BOTOX® should only be prescribed for you for chronic migraine if you have been diagnosed by a doctor who is specialised in this area, like a neurologist. BOTOX® is not used for acute migraine, chronic tension type headaches or patients with medication overuse headache.

Method and route of administration

BOTOX® is injected into your muscles (intramuscularly), into the bladder wall via a specific instrument (cytoscope) to inject into the bladder or into the skin (intradermally). It is injected directly into the affected area of your body; your doctor will usually inject BOTOX® into several sites within each affected area.

General information about dosage

Your medical practitioner will decide how much, how often, and in which muscle(s) BOTOX® will be given to you.

If you have received more BOTOX® than you should

The signs of too much BOTOX® may not appear for several days after the injection. Should you swallow BOTOX® or have it accidentally injected, you should see your doctor who might keep you under observation for several weeks.

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If you have received too much BOTOX®, you may have any of the following symptoms and you must contact your doctor immediately. He/she will decide if you have to go to hospital:

- Muscle weakness which could be local or distant from the site of injection;
- Difficulty in breathing, swallowing or speaking due to muscle paralysis;
- Food or liquid accidentally going into your lungs which might cause pneumonia (infection of the lungs) due to muscle paralysis;
- Drooping of the eyelids, double vision;
- Generalised weakness.

If you have any further questions on the use of BOTOX®, ask your doctor or pharmacist.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest poison control centre.

4. Possible side effects

BOTOX® can have side effects. Not all side effects reported for BOTOX® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving BOTOX®, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens after receiving BOTOX®, tell your doctor immediately or go to the casualty department at your nearest hospital:

- **If you have any difficulty in breathing, swallowing or speaking;**
- **If you experience hives, swelling including swelling of the face or throat, wheezing, feeling faint and shortness of breath.**

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These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BOTOX®. You may need urgent medical attention or hospitalisation.

Side effects usually occur within the first few days following injection and may last for several months or, in some cases, longer.

Below are lists of side effects which vary depending on the part of the body where BOTOX® is injected:

Injections for children with persistent muscle spasms in upper limb

Frequent	Upper respiratory tract infection, nausea, muscle weakness, pain where the injection was given

Injections for children with persistent muscle spasms in the lower limb

Frequent	Stretching or tearing of ligaments, shallow wound to the skin, problems with walking, pain where the injection was given, rash
Less frequent	Muscle weakness

There have been reports of death in children with severe cerebral palsy after treatment with BOTOX®.

Injections in the hand, arm and shoulder of adult patients

Frequent	Nausea, pain in the hand and fingers, muscle weakness, tiredness, swelling of the extremities such as the hands and feet

Injections in the lower limb of adult patients

Frequent	Rash, joint pain or inflammation, stiff or sore muscles, muscle weakness, swelling of the extremities such as the hands and feet, fall

Injections in the eye muscles

Frequent	Drooping of the eyelid, problems with eye movement
Less frequent	Bleeding behind the eyeball, penetration of the needle into the eye, pupil defects, bleeding in the vitreous (jellylike substance that fills the back of the eyeball)

Injections in the eyelid and face

Frequent	Drooping of the eyelid, pinpoint damage of the cornea (transparent surface covering the front of the eye), difficulty in completely closing the eye, dry eyes; sensitivity to light, eye irritation, overflow of tears, bruising under the skin, skin irritation, swelling of the face
Less frequent	Dizziness, weakness of the face muscles, drooping of the muscles on one side of the face, inflammation of the cornea (transparent surface covering the front of the eye), abnormal turning of the eyelids (outwards or inwards), double vision, difficulties in seeing clearly, blurred vision, rash, tiredness, swelling of the eyelid, ulcer, damage to the cornea (transparent surface covering the front of the eye)

Injections in the neck and shoulder

Frequent	Swelling and irritation inside the nose (rhinitis), blocked or runny nose, cough, sore throat, tickle or irritation in the throat, dizziness, increased muscle tension (cramps), decreased skin sensation, sleepiness, headache, difficulty in swallowing, dry mouth, nausea, muscle weakness, stiff or sore muscles, pain,

	feeling of weakness, flu syndrome, feeling generally unwell
Less frequent	Double vision, drooping of the eyelid, shortness of breath, changes in your voice, fever

Injections in the head and neck for the treatment of headache in patients who suffer from chronic migraine

Frequent	Headache, migraine and worsening of migraine, weakness of the face muscles, drooping of the eyelid, itching, rash, neck pain, muscle pain, muscle stiffness, muscle spasm, muscle tightness, muscle weakness, pain where the injection was given
Less frequent	Skin pain, jaw pain, difficulty in swallowing

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

Frequent	Urinary tract infection, painful urination after the injection*, bacteria in the urine, inability to empty your bladder (urinary retention), incomplete emptying of the bladder, frequent daytime urination, white blood cells in the urine, blood in urine after injection**

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

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

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

Frequent	Urinary tract infection, inability to empty your bladder (urinary retention), difficulty in sleeping (insomnia), constipation, muscle weakness, muscle spasm, blood in the urine after the injection*, painful urination after the injection*, bulge in the bladder wall (bladder diverticulum), tiredness, problems

	with walking (gait disturbance), possible uncontrolled reflex reaction of your body (e.g. profuse sweating, throbbing headache or increase in pulse rate) around the time of the injection (autonomic dysreflexia)*, fall

* Some of these common side effects may also be related to the injection procedure

Injections for excessive sweating of the armpits

Frequent	Pain where the injection was given, headache, numbness, hot flushes, nausea, increased sweating at sites other than the armpit, abnormal skin odour, itching, lump under the skin, hair loss, pain in the extremities such as the hands and fingers, pain, swelling, bleeding, increased sensitivity, irritation or reactions where the injection was given, general weakness
Less frequent	Muscle weakness, feeling of weakness, muscle pain, problem with the joints

Injections for the temporary improvement in the vertical lines between the eyebrows

Frequent	Headaches, numbness, drooping eye lid, nausea, skin redness, skin tightness, localised muscle weakness, face pain, bruising under the skin, swelling, pain or irritation where the injection was given
Less frequent	Infection, anxiety, dizziness, inflammation of the eyelid, eye pain, visual disturbance (including blurred vision), dry mouth, swelling (face, eyelid, around the eyes), sensitivity to light, itching, dry skin, muscle twitching, flu syndrome, general weakness, fever

Injections for the temporary improvement in the fan-shaped lines from the corner of the eyes, when treated with or without vertical lines between the eyebrows seen at frown

Frequent	Swelling of the eyelid injection site bleeding, injection site bruising
Less frequent	Injection site pain, injection site tingling or numbness

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Injections for the temporary improvement in the forehead lines and vertical lines between the eyebrows seen at frown when treated with or without the fan-shaped lines from the corner of the eyes

Frequent	Headaches, drooping eyelid, skin tightness (including Mephisto sign [raising of the outer eyebrows]), injection site bruising
Less frequent	Drooping eyebrow, injection site pain

Injections for the temporary improvement in the appearance of vertical neck bands connecting the jaw and neck (platysma prominence)

Less frequent	Facial muscle weakness, difficulty swallowing

The following list describes additional side effects reported for BOTOX® since it has been marketed: heart problems, decreased hearing, noises in the ear, feeling of dizziness or "spinning" (vertigo), increase in eye pressure, drooping eyelid, strabismus (crossed-eyes), blurred vision, difficulties in seeing clearly, abdominal pain, diarrhoea, constipation, dry mouth, difficulty swallowing, nausea, vomiting, loss of nerve supply to injected muscle, feeling generally unwell (malaise), fever, allergic reaction, including reactions to injected proteins or serum, swelling of the deeper layers of the skin, hives, eating disorders, loss of appetite, shrinkage of injected muscle, muscle pain, nerve damage (brachial plexopathy), voice and speech problems, weakness of the face muscles, decreased skin sensation, muscle weakness, chronic disease affecting the muscles (myasthenia gravis), difficulty moving the arm and shoulder, numbness, pain, numbness or weakness starting from the spine, seizures, fainting, droop of muscles on one side of the face, aspiration pneumonia (lung inflammation caused by accidentally breathing in food, drink, saliva or vomit); breathing problems, respiratory depression, respiratory failure, hair loss, drooping eyebrow, psoriasis-like skin patches, different types of red blotchy skin rashes, excessive sweating, loss of eyelashes or eyebrows, itching, rash, difficulty in completely

closing the eye, dry eye, localised muscle twitching / involuntary muscle contractions, swelling of the eyelid, Mephisto sign (raising of the outer eyebrows).

Reporting of side effects

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of BOTOX®.

In case of a side effect, please contact MEAPV@abbvie.com

5. How to store BOTOX®

- Store all medicines out of the reach of children.
- Store in a refrigerator (2 °C – 8 °C), or store in a freezer (at or below - 5 °C).
- After the solution is made up, immediate use of the solution is recommended; however it can be stored for up to 24 hours in a refrigerator (2 °C – 8 °C).
- Your doctor should not use BOTOX® after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). In the event of a spillage, a diluted solution of household bleach may be used to deactivate the medicine for five minutes before disposing as medical waste.

6. Contents of the pack and other information

What BOTOX® contains

- The active substance is botulinum toxin type A from Clostridium botulinum.
- The other ingredients are human albumin and sodium chloride.

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What BOTOX® looks like and contents of the pack

BOTOX® is a white, vacuum dried powder for solution for injection and is supplied in a transparent glass vial containing 50 Units, 100 Units or 200 Units of botulinum toxin type A. Each vial is packed in an outer carton. Prior to injection, the product must be dissolved in a sterile, unpreserved saline solution. Dissolved BOTOX® is a clear colourless to slightly yellow solution free of any particles.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

For the professional information please email medicalinfo.za@abbvie.com

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