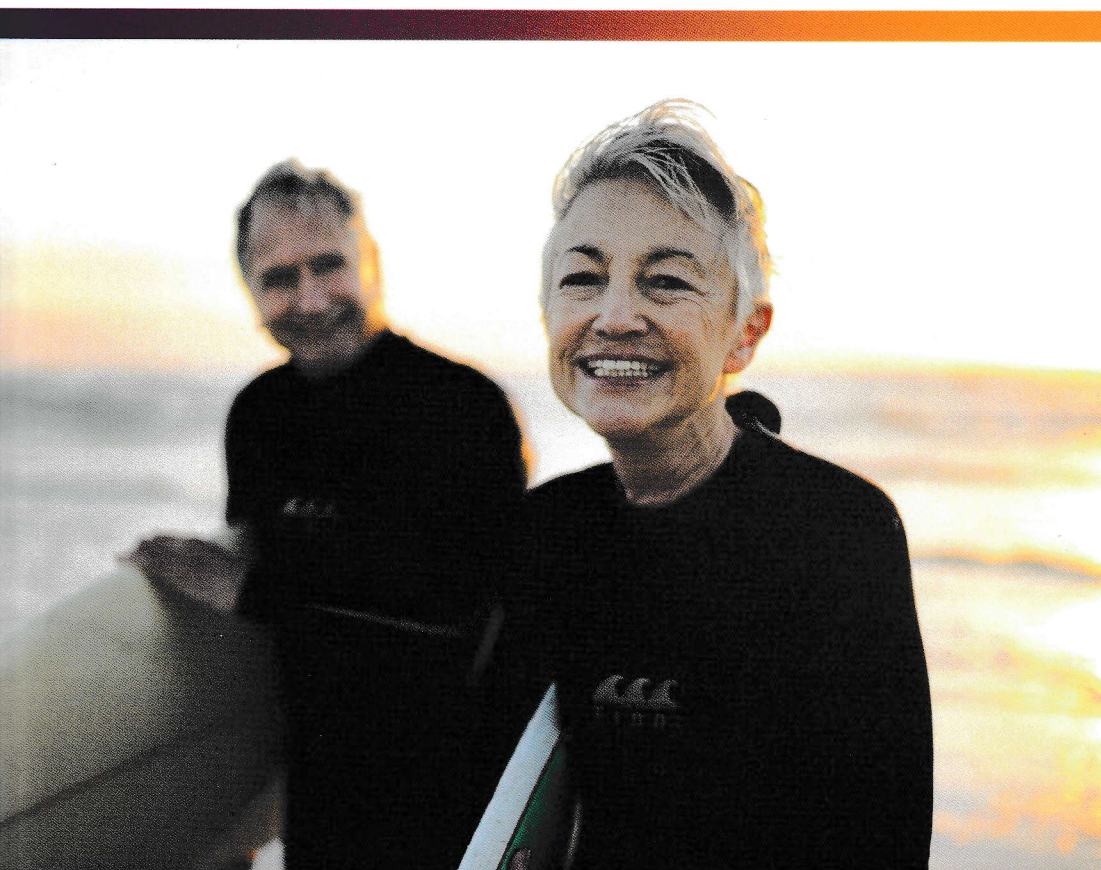




TREATMENT FOR OVERACTIVE BLADDER

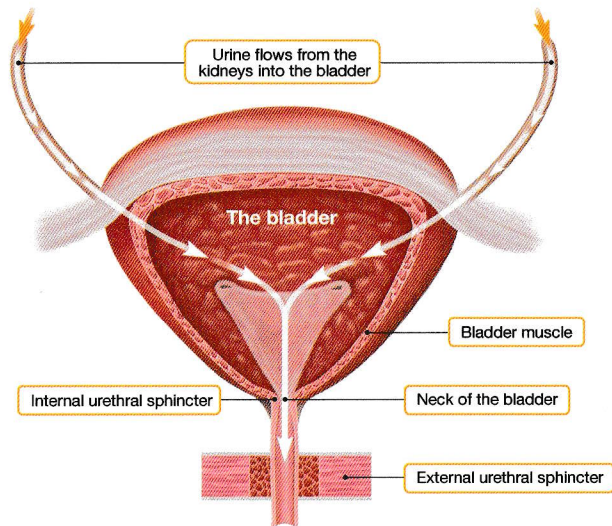
INFORMATION FOR PATIENTS AND CARERS



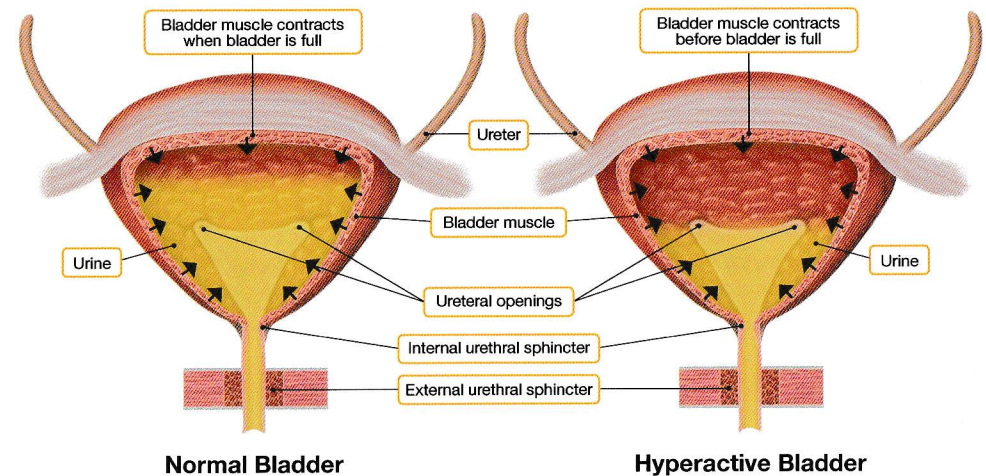
This booklet has been provided to you because your doctor has prescribed or recommended BOTOX® (botulinum toxin type A) treatment for Overactive Bladder.

WHAT IS OVERACTIVE BLADDER?

Normal bladder function - to store urine as it is produced so that you can release urine at a time and place that is suitable and convenient for you. As more and more urine is produced the bladder stretches like a balloon to hold it. Eventually, it becomes so stretched and full of urine that the nerves in the bladder send a signal to the brain, via the spinal cord, that it needs to empty. When your brain gets this message, it tells you to find a toilet. When you're ready to empty the bladder the brain sends signals, via the spinal cord, to tell the pelvic floor muscles to relax and the bladder muscle to contract to push out all the urine. Then the whole process can start again. During the course of a day, an average person will need to pass urine up to 8 times. The rest of the time the bladder is in 'storage mode', quietly storing urine and allowing us to focus on our daily lives.



Overactive Bladder - may happen when the nerve signals between your brain and your bladder tell your bladder to empty even when it isn't full. Also, it can occur when the muscles in your bladder are overactive and contract before your bladder is full. The result is a sudden, strong urge to urinate that you cannot control known as 'urgency', which is the most common symptom of overactive bladder. You may be worried that you won't make it to the bathroom in time. You may or may not leak urine after feeling this urge.



The number of times a person urinates during the day varies from person to person, but many experts consider urinating more than eight times in 24 hours as 'frequent urination'. Waking up more than once a night to urinate is another symptom called 'nocturia'.

Overactive Bladder is a chronic and debilitating condition that can have a profound effect on quality of life, including physical, psychological, and limiting daily social and work activities. Many people with Overactive Bladder restrict social activities they once enjoyed, and experience seclusion and psychological stress. Embarrassment, loss of confidence, anxiety and depression are common responses to the symptoms. Overactive Bladder is under-reported and often inadequately treated as people may be embarrassed, have a view that symptoms are an inevitable result of ageing, have an assumption that effective treatment is unavailable, a fear of treatment or poor communication about the condition with their doctors.

BOTOX® INJECTION FOR OVERACTIVE BLADDER

What is BOTOX® injection?

BOTOX® injection is a natural, purified protein which has the ability to relax muscles. The active ingredient is botulinum toxin type A which is extracted from bacteria, under controlled laboratory conditions, in much the same way penicillin is produced from a mould.

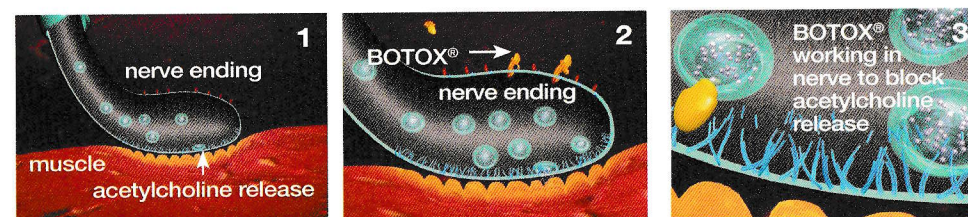
BOTOX® injection is a prescription only medication that should only be administered by a qualified medical professional.

BOTOX® injection has been used in Australia and New Zealand for over 20 years to treat many neurological, pain and movement disorders such as juvenile cerebral palsy and urine leakage caused by neurological illnesses (such as spinal cord damage and multiple sclerosis).



How does BOTOX® treatment work?

A muscle contracts when the brain sends chemical messengers (neurotransmitters) to the muscle telling it to tighten. BOTOX® treatment works by temporarily stopping the release of a specific neurotransmitter called acetylcholine and therefore stops the message to 'tighten' from reaching the muscle. By injecting BOTOX® into the muscles responsible for the contractions, the messages telling the muscle to contract are stopped and the muscle is then able to relax.



BOTOX® works on the bladder nerves to relax the bladder to:

- Reduce bladder contractions
- Reduce the occurrence of urine leakage
- Reduce the feeling of needing to go to the toilet very suddenly
- Reduce how often you feel the need to pass urine

What does BOTOX® treatment involve?

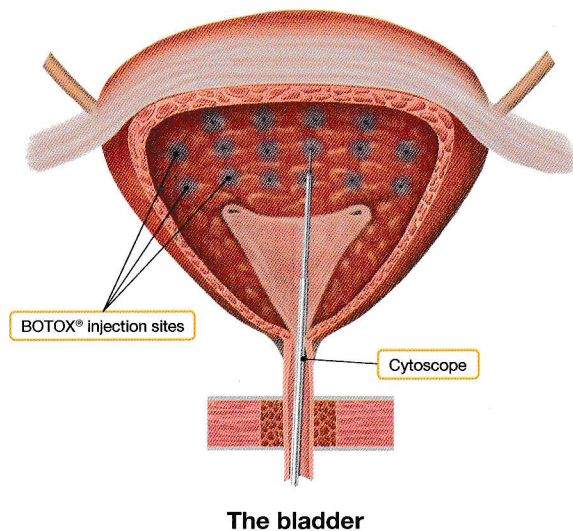
Before recommending BOTOX® treatment, your doctor will have carried out a number of tests to check that it is a suitable treatment for you. They should also have had a discussion with you to explain what it involves, so you can decide if it's right for you.

As the bladder will be 'relaxed' by the BOTOX® treatment, some people find that they cannot completely empty their bladder without using a technique known as Clean Intermittent Catheterisation (CIC). Not everybody who has BOTOX® needs to use CIC, but it is a possibility you should be aware of and your doctor will explain what you need to do. Once you're able to manage CIC, you'll probably only need to go to the toilet to empty your bladder every 3-4 hours, when it's convenient for you.

If you decide to go ahead with the treatment, your doctor will also need to check that you do not have a urinary tract infection (UTI) at the time of treatment. You will also need a short course of antibiotics to help prevent infection. If you are taking certain medicines such as anti-platelets (aspirin-like products) and/ or anti-coagulants (blood thinners), your doctor will talk to you about temporarily stopping these.

A general overview:

- Your treatment with BOTOX® will take place in a hospital or day procedure facility
- Your doctor will discuss with you the options of a general or local anaesthetic to minimise the discomfort of the procedure
- To put the BOTOX® into your bladder, your doctor will use a cystoscope. This is a fine tube, containing a tiny camera, that enables doctors to see inside the bladder
- Your doctor will inject tiny amounts of BOTOX® into the muscle of your bladder. The whole procedure should be over in about 30 minutes
- Most people who have had BOTOX® treatment in the bladder describe it as 'uncomfortable' but not painful



After BOTOX® treatment

If you respond to BOTOX® treatment, improvement generally occurs within 2 weeks after treatment. The BOTOX® treatment effects may last for approximately 5 - 6 months, and then you will need to be re-treated to continue experiencing the effects. Treatments can be repeated as long as your condition responds to BOTOX® and you do not have any serious allergic reactions or other significant side effects to the treatment.

It is important that you follow your doctor's care advice after you have received BOTOX® treatment in the bladder.

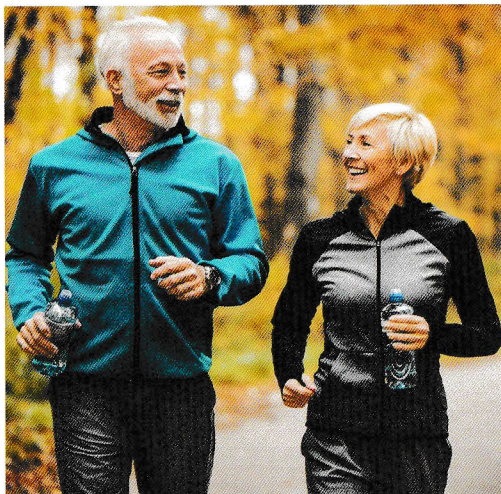
- You may be given another short course of antibiotics to help prevent infection
- You must contact your doctor at any time if you are unable to pass urine
- At your review visit, how well your bladder is emptying may be checked
- Hopefully, your bladder will be emptying well, but if it isn't your doctor will talk to you about what you can do
- Your doctor may book you in for a treatment review around 6 months or will ask you to call when your symptoms re-present to review repeat treatment



Are there side-effects with BOTOX® treatment?

BOTOX® treatment is generally well tolerated. The most common side effects seen with BOTOX® treatment for Overactive Bladder are: urinary tract infection and/or painful urination after the injection (may be caused by the injection procedure).

Other common side effects include bacteria in the urine, inability to empty your bladder (urinary retention), incomplete emptying of the bladder, frequent daytime urination and/or blood in the urine after the injection (may be caused by the injection procedure).



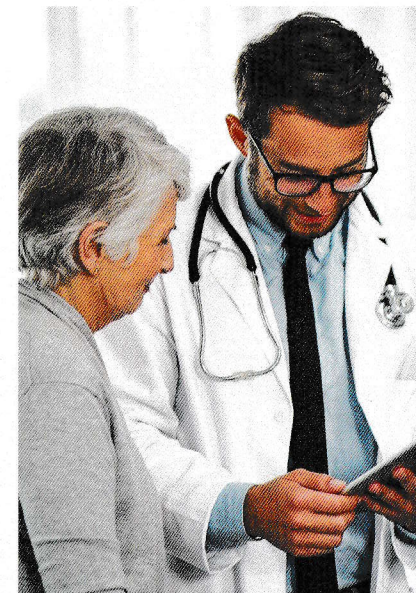
You should contact your doctor immediately if you experience any of the following:

- Difficulty in breathing, swallowing or speaking
- Sudden urinary tract infection (a burning sensation on passing urine and a temperature over 38°C)
- Increase in voiding frequency or increase in incontinence
- Sudden inability to, or difficulty with, emptying your bladder (urinary retention)
- Severe allergic reaction (hives, swelling including swelling of the face/throat, wheezing, feeling faint and shortness of breath)

If you have any concerns or further questions regarding side effects, please contact your doctor.

It is important to tell your doctor if you:

- are being treated for leakage of urine due to overactive bladder and have diabetes
- have received any other botulinum toxin product in the last four months
- have recently received an antibiotic by injection, such as gentamycin or tobramycin
- if you have had any swelling or weakness
- are scheduled to have surgery using a general anaesthetic
- are taking any prescription medicines
- are taking medications that may interfere with muscle function
- are taking other medications, including those that you have bought at your pharmacy, supermarket or health food shop
- have problems with your heart or circulation
- are pregnant or have the intention of becoming pregnant
- are breastfeeding or planning to start breastfeeding



BOTOX® injection must not be used if you:

- are allergic to any of the following ingredients: clostridium botulinum toxin type A-haemagglutinin complex, human albumin or sodium chloride
- have an infection in the muscles where it would normally be injected
- have any muscle disorders in other parts of your body, such as myasthenia gravis or Eaton Lambert Syndrome

If you have any further questions about your treatment, please ask your doctor.
The complete BOTOX® Consumer Medicine Information can be read online:

Australia - www.tga.gov.au

New Zealand - www.medsafe.govt.nz

NOTES

This image shows a single sheet of white paper with horizontal blue or grey ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

For New Zealand patients: BOTOX® is a prescription medicine containing 100 units of botulinum toxin type A for injection. **It is used for the treatment of overactive bladder with the 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.** It should only be administered by trained medical professionals. Do not use if you have myasthenia gravis, Eaton Lambert Syndrome or infection at the proposed injection site. **Caution:** People with amyotrophic lateral sclerosis or other neuromuscular junctional disorders, concomitant use with aminoglycoside antibiotics or other medicines that interfere with neuromuscular junctional disorders, inflammation at the site of injection, excessive weakness in the muscles to be injected, fixed contractures, pregnancy and lactation. Caution should be exercised when treating patients with significant disability. **Adverse effects** reported after injection of BOTOX® for overactive bladder with the leakage of urine, the sudden urge to empty your bladder and needing to go to the toilet more than usual when an anticholinergic drug did not help have included urinary tract infection, presence of bacteria in your urine, painful or difficult urination and retention of urine. **Funding:** BOTOX® is available under section H of the PHARMAC Pharmaceutical Schedule, no restrictions apply. It is not subsidised under the general PHARMAC Pharmaceutical Schedule and patients will need to pay for BOTOX® when prescribed outside schedule H conditions and normal doctor visit fees will apply.

BOTOX® treatment has risks and benefits. Ask your doctor if BOTOX® treatment is right for you. For further information the Data Sheet and Consumer Medicines Information can be accessed at www.medsafe.govt.nz or ask your doctor. If symptoms persist or if you have side effects, please see your doctor.

My next appointment is:

Time:

Allergan Australia Pty Ltd. Level 20, 177 Pacific Highway, North Sydney NSW 2060. ABN 85 000 612 831.

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