



Treatment

Botox[®] (botulinum toxin type A)

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Botox[®] (botulinum toxin type A)

There are therapies available for treating specific symptoms of multiple sclerosis that work without altering the course of the disease. This includes treatments for muscle problems such as stiffness and tremors, fatigue, neurological symptoms such as visual disturbances, incontinence and neuropsychological problems such as depression, anxiety or memory difficulties.

What is Botox[®] (botulinum toxin type A) and how does it work?

Botox[®] is a pharmaceutical preparation of the botulinum toxin type A produced by the bacterium *Clostridium botulinum*, which has muscle relaxant properties. It can be used in people living with multiple sclerosis for the relief of focal muscle spasticity (spasticity that is localised to a particular region of the body such as the hand, arm or leg) and for the treatment of urinary incontinence due to neurogenic overactivity of the detrusor muscle.

This fact sheet refers to the use of Botox[®] for urinary incontinence only. For the treatment of urinary incontinence, Botox[®] is generally offered only to patients for whom other treatments, such as anticholinergic drugs, have failed.

The clinical criteria for use of Botox[®] for urinary incontinence includes:

- The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study
- The condition must be inadequately controlled by anti-cholinergic therapy
- Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment

- Patient must be willing and able to self-catheterise
- The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6–12 weeks after the first treatment.

In Australia, botulinum toxin type A is sold under the brand name Botox[®].

In clinical trials¹ Botox[®] has been shown to:

- reduce the number of urinary incontinence episodes²
- improve urodynamic measures such as maximum capacity to contract and expel urine, maximum detrusor muscle pressure and improve scores on the Incontinence Quality of Life measure².



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How is Botox[®] administered?

Botox[®] works by temporarily relaxing overactive muscles. It is administered through an injection directly into the muscle. In the case of urinary incontinence, injections are made directly into the bladder wall (the detrusor muscle). The treatment is administered by a doctor in the form of multiple injections into the muscle using a specific instrument called a cystoscope. The total Botox[®] dose is 200 units.

Botox[®] usually begins to work within two weeks of the injection and lasts between eight and 10 months for urinary incontinence due to neurogenic detrusor overactivity. Once the effects begin to wear off, the treatment can be repeated, but not more often than every three months.

What are the potential side effects of Botox[®] treatment?

The treatment does have side effects. Common side effects include urinary tract infection and urinary retention. Intermittent self-catheterisation may be necessary. Other, less common, side effects include difficulty sleeping, constipation, muscle weakness and spasm, bulge in the bladder wall, tiredness and problems with walking and falls. There may also be side

effects directly related to the injection procedure such as blood in the urine after the injection.

Botox[®] is not recommended during pregnancy. It should not be used by pregnant women or women of childbearing age who are not using effective birth control.

How much does Botox[®] cost?

Botox[®] has been approved by the Therapeutic Goods Administration for the treatment of urinary incontinence due to neurogenic detrusor overactivity in multiple sclerosis and is available on the Pharmaceutical Benefit Scheme (PBS).

Please discuss with your neurologist whether Botox[®] is the right treatment for you. There are a number of criteria you must meet before your doctor can receive authority to write this prescription.

For details of the criteria required to receive a prescription for Botox[®] treatment through the PBS, please visit the official PBS website at:

www.pbs.gov.au/medicine/item/6103F

You will need to click on the red **Authority Required (STREAMLINED)** link.

If you are eligible for medications through the PBS, you will need to pay a contribution fee each time your prescription is dispensed. The Federal Government pays

for the remaining cost. The amount of the contribution fee depends upon whether or not you have a pension or concession card. The amount of this fee is set each year by the Federal Government.

Further information about the PBS, your entitlements and details regarding the PBS safety net (which protects patients and their families requiring a large number of PBS items) is available through the Medicare Australia website at: **www.medicare.gov.au**

If you are not eligible for Botox[®] through the PBS, for example if you are a visitor from overseas, a neurologist, urologist or urogynaecologist may write a private prescription and you will have to pay the full cost at the pharmacy that dispenses the medication. Pharmacists can provide a quote for the price of any medication which is not subsidised by the PBS.



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General information

In Australia Botox[®] is supplied by:
Allergan Australia Pty Ltd
Level 4, 810 Pacific Highway
Gordon NSW 2072

For more information on multiple sclerosis and other multiple sclerosis treatments

- Speak to your neurologist about what treatment best suits your individual circumstances.
- MS nurses can also provide information, training and ongoing support in managing your immunotherapy.
- For information about multiple sclerosis, multiple sclerosis treatment and to find contact details for your state MS organisation visit www.ms.org.au
- MS Research Australia provides information on the latest research and clinical trials at www.msra.org.au

References

1. Botox[®] Approved Product Information, September 2015
www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-07059-3
2. Cruz F, Herschorn S, Aliotta P, Brin M, Thompson C, Lam W, Daniell G, Heesakkers J, Haag-Molkenteller C. Efficacy and safety of onabotulinumtoxinA in patients with urinary incontinence due to neurogenic detrusor overactivity: a randomised, double-blind, placebo-controlled trial. *Eur Urol.* 2011; 60(4):742-50.

Note

MS does not recommend any specific disease-modifying treatment for people living with multiple sclerosis. Decisions about any treatments, taking into consideration the potential benefits and side effects for each individual's circumstances, should be made in careful consultation with the person's neurologist.

The information supplied in this document is collated from material provided by the relevant pharmaceutical company, MIMS (www.mims.com.au) and MS Research Australia.