



Pharmaceutical Services Branch information bulletin

Prescribing and administration of botulinum toxin (Botox[®], Dysport[®])

Who should read this information?

This information is intended for medical practitioners, nurses, those working in cosmetic clinics (including beauty therapists) and patients receiving these services.

Botulinum toxin

Botulinum toxin is a medicine also known by brand names such as Botox[®] or Dysport[®].

It comes from the bacterium, *Clostridium botulinum*, also responsible for botulism food poisoning.

Botulinum toxin blocks release of the neurotransmitter acetylcholine from motor nerve terminals. The resulting chemical denervation causes localised muscle weakness or paralysis.

Adverse effects

It is common to experience local pain, tenderness and bruising after injection.

Botulinum toxin can cause serious adverse events related to its therapeutic actions if it spreads past the muscle injected.

Ptosis (drooping eyelid), diplopia (double vision), difficulty swallowing and speaking, general weakness and respiratory failure are uncommonly reported.

Deaths have occurred in patients who also have other significant illnesses.

Botulinum toxin can cause hypersensitivity reactions (including reactions to albumin components).

Muscular disorders such as myasthenia gravis and Eaton Lambert Syndrome are a contraindication to use.

Botulinum toxin is a prescription medicine

Botulinum toxin is a prescription only medicine. Safe use of these products requires proper medical oversight due to:

- risks from the medication itself
- risks from administration (injection)
- complexity of conditions being treated.

Storage and use

Botulinum toxin comes as vials of sterile powder. It must be reconstituted with sterile saline before injection. The volume used depends on the condition being treated, size of the muscle injected and risk of spread.

The products must be refrigerated both before and after reconstitution. Once reconstituted, the product should be used within 24 hours. Botulinum toxin is usually given as an intramuscular injection, or intradermally for hyperhidrosis (excessive sweating).

Medicines and the law

Prescribing and administration of medicines is controlled by the *Poisons Act 1964* and the Poisons Regulations 1965.

Only a registered health practitioner authorised to prescribe prescription medicines can authorise the administration of botulinum toxin to a patient.

The authorised prescriber must be lawfully practising their profession and acting within their professional scope of practice.

Only a medical practitioner or a nurse practitioner (with an approved Clinical Practice Guideline relating to botulinum toxin) may prescribe this medicine.

Administration

An authorised practitioner may direct a registered nurse to administer botulinum toxin to a patient.

This direction to administer should be in writing and specify:

- the medicine and dose to be given
- the route and site(s) of administration
- how many times and it may be repeated
- when it may be repeated.

An administration direction may be valid for up to 12 months.

Record keeping

Poisons Regulations require the administration or supply of prescription medicines to be recorded in the patient's medical notes. The practitioner must record the:

- medicine name, strength and quantity
- date of administration or supply.

These records must be kept for two years.

Other legal concerns

A Registered Nurse may administer a prescription medicine, such as botulinum toxin, under the direction of an authorised prescriber, such as a medical practitioner.

Outside these provisions, a Registered Nurse has no authority to independently purchase, obtain, administer or supply prescription medicines.

The Medical Board of Australia outlines best practice for prescribing a treatment for administration or supply in *Good Medical Practice: A Code of Conduct for Doctors in Australia*.

The Code stipulates that prior to prescribing, a medical practitioner must assess the patient and take into account the medical history and results of an appropriate physical examination.

More information

For more information on the prescribing and administration of medicines or poisons legislation in Western Australia, please contact the Pharmaceutical Services Branch on 9222 6883 (Monday to Friday 8.30am – 4.30pm) or poisons@health.wa.gov.au