Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

BOTOX 100 Allergan Units powder for solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

botulinum toxin* type A, 100 Allergan Units/vial.
* from *Clostridium botulinum*
Botulinum toxin units are not interchangeable from one product to another.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for solution for injection.
Product imported from Greece and Czech Republic:
White powder.
BOTOX product appears as a thin white deposit that may be difficult to see on the base of the vial.

4 CLINICAL PARTICULARS

As per PA1824/017/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1824/017/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Human albumin
Sodium chloride

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the vial and outer carton of the product as marketed in the country of origin.
Potency studies have demonstrated that the product may be stored for up to 5 days at 2 – 8°C following reconstitution.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution (etc) has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C), or store in a freezer (-5°C to -20°C).

For storage conditions of the reconstituted medicinal product see section 6.3.

6.5 Nature and contents of container

Glass vial with rubber stopper and tamper evident aluminium seal.

6.6 Special precautions for disposal

It is good practice to perform vial reconstitution and syringe preparation over plastic-lined paper towels to catch any spillage.

BOTOX must only be reconstituted with sterile unpreserved 0.9% sodium chloride for injection. The appropriate amount of diluent should be drawn up into a syringe. See below for dilution instructions.

Dilution table for BOTOX 100 Allergan Units vial size for all indications except bladder disorders:

	100 Unit vial
Resulting dose (Units per 0.1 ml)	**Amount of diluent* added in a 100 Unit vial**
20 Units	**0.5 ml**
10 Units	**1 ml**
5 Units	**2 ml**
2.5 Units	**4 ml**
1.25 Units	**8 ml**

* sterile unpreserved 0.9% sodium chloride solution for injection

Overactive bladder:
It is recommended that a 100 Unit or two 50 Unit vials are used for convenience of reconstitution.

Dilution instructions using a 100 Unit vial	• **Reconstitute a 100 Unit vial of BOTOX with 10 ml of sterile unpreserved 0.9% sodium chloride solution for injection and mix gently.** • **Draw the 10 ml from the vial into a 10 ml syringe.**

This will result in a 10 ml syringe containing a total of 100 Units of reconstituted BOTOX. Use immediately after reconstitution in the syringe. Dispose of any unused sodium chloride solution.
This product is for single use only and any unused reconstituted product should be disposed of.

Urinary incontinence due to neurogenic detrusor overactivity:
It is recommended that a 200 Unit vial or two 100 Unit vials are used for convenience of reconstitution.

Dilution instructions using two 100 Unit vials	• **Reconstitute two 100 Unit vials of BOTOX, each with 6 ml of sterile unpreserved 0.9% sodium chloride solution for injection and mix the vials gently.** • **Draw 4 ml from each vial into each of two 10 ml syringes.** • **Draw the remaining 2 ml from each vial into a third 10 ml syringe.** • **Complete the reconstitution by adding 6 ml of sterile unpreserved 0.9% sodium chloride solution for injection into each of the three 10 ml syringes, and mix gently.**

This will result in three 10 ml syringes containing a total of 200 Units of reconstituted BOTOX. Use immediately after reconstitution in the syringe. Dispose of any unused sodium chloride solution.
If different vial sizes of BOTOX are being used as part of one injection procedure, care should be taken to use the correct amount of diluent when reconstituting a particular number of units per 0.1 ml. The amount of diluent varies between BOTOX 50 Allergan Units, BOTOX 100 Allergan Units and BOTOX 200 Allergan Units. Each syringe should be labelled accordingly. Since BOTOX is denatured by bubbling or similar vigorous agitation, the diluent should be gently injected into the vial. The vial should be discarded if a vacuum does not pull the diluent into the vial. Reconstituted BOTOX is a clear colourless to slightly yellow solution free of particulate matter. The reconstituted solution should be visually inspected for clarity and absence of particles prior to use. When reconstituted in the vial, BOTOX may be stored in a refrigerator (2 - 8°C) for up to 24 hours prior to use. If BOTOX is further diluted for intradetrusor injection in a syringe, it should be used immediately. This product is for single use only and any unused solution should be discarded.

For safe disposal, unused vials should be reconstituted with a small amount of water and then autoclaved. Any used vials, syringes, and spillages etc. should be autoclaved, or the residual BOTOX inactivated using dilute hypochlorite solution (0.5%) for 5 minutes.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/521/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th January 2026

10 DATE OF REVISION OF THE TEXT

March 2026