Public Summary

Summary for ARTG Entry:	67311 BOTOX botulinum toxin, type A purified neurotoxin complex 100U injection vial
ARTG entry for	Medicine Registered
Sponsor	Abbvie Pty Ltd
Postal Address	Locked Bag 5029, BOTANY, NSW, 1455 Australia
ARTG Start Date	9/07/1999
Product Category	Medicine
Status	Active
Approval Area	Drug Safety Evaluation Branch

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 February 1992, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 February 1992, other than condition No. 11.

Except where the sponsor has been contracted by an overseas partry to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

Products

1 . BOTOX botulinum toxin, type A purified neurotoxin complex 100U injection vial

Product Type	Single Medicine Product	**Effective Date**	1/02/2024

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

BOTOX (Botulinum toxin type A) purified neurotoxin complex is indicated for the following therapeutic indications: Treatment of overactive bladder with symptoms of urinary incontinence, urgency, and frequency, in adult patients who have an inadequate response to or are intolerant of an anticholinergic medication. Treatment of urinary incontinence due to neurogenic detrusor overactivity resulting from a defined neurological illness (such as spinal cord injury or multiple sclerosis) and not controlled adequately by anticholinergic agents. Prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine). Treatment of strabismus in children and adults.Treatment of blepharospasm associated with dystonia, including benign blepharospasm and VIIth nerve disorders (specifically hemifacial spasm) in patients twelve years and older. Treatment of cervical dystonia (spasmodic torticollis). Treatment of focal spasticity of the upper and lower limbs, including dynamic equinus foot deformity, due to juvenile cerebral palsy in patients two years and older. Treatment of severe primary hyperhidrosis of the axillae. Treatment of focal spasticity in adults. Treatment of spasmodic dysphonia. BOTOX (botulinum toxin type A) purified neurotoxin complex is indicated for the following cosmetic indications: temporary improvement in the appearance of upper facial rhytides (glabellar lines, crow's feet and forehead lines) in adults.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	3 Years	Store at 2 to 8 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
1 x 100U vial	(S4) Prescription Only Medicine

Components

1 . BOTOX botulinum toxin, type A purified neurotoxin complex 100U injection vial

Dosage Form	Injection, powder for
Route of Administration	Intradermal Intramuscular Subcutaneous
Visual Identification	White powder

Active Ingredients

Botulinim toxin type a	**100 U**

Other Ingredients (Excipients)

Albumin

sodium chloride

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