

Public Summary

Summary for ARTG Entry: 202519 CAVERJECT alprostadil 20 microgram powder for injection vial with diluent syringe

ARTG entry for Medicine Registered
Sponsor Pfizer Australia Pty Ltd
Postal Address 38-42 Wharf Road, WEST RYDE, NSW, 2114
 Australia
ARTG Start Date 4/02/2013
Product category Medicine
Status Active
Approval area Drug Safety Evaluation Branch

Conditions

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.

Products**1. CAVERJECT alprostadil 20 microgram powder for injection vial with diluent syringe**

Product Type	Composite Pack	Effective date	26/05/2016
--------------	----------------	----------------	------------

Warnings

See Product Information and Consumer Medicine Information for this product

Standard Indications**Specific Indications**

Intracavernosal alprostadil (PGE1) is indicated for the treatment of erectile dysfunction in adult males. Intracavernosal alprostadil may be a useful adjunct to other diagnostic tests in the diagnosis of erectile dysfunction.

Additional Product information**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	2 Years	Store below 25 degrees Celsius	Not recorded	Protect from Moisture

Pack Size/Poison information**Pack Size**

1 vial + 1 prefilled syringe of diluent
 10 vials + 10 prefilled syringes of diluent
 5 vials + 5 prefilled syringes of diluent

Poison Schedule

(S4) Prescription Only Medicine
 (S4) Prescription Only Medicine
 (S4) Prescription Only Medicine

Components**1. Diluent****Dosage Form**

Injection, solution

Route of Administration

Intracavernosal

Visual Identification

Clear colourless liquid.

2. Powder**Dosage Form**

Injection, powder for

Route of Administration

Intracavernosal

Visual Identification

White to off-white powder.

Active Ingredients

Alprostadil

20 microgram

Public Summary