Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	11290 Pfizer (Australia) SODIUM CHLORIDE 0.9% irrigation solution ampoule
ARTG entry for	Medicine Registered
Sponsor	Pfizer Australia Pty Ltd
Postal Address	Level 17 151 Clarence Street, Sydney, NSW, 2000 Australia
ARTG Start Date	13/08/1991
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"

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 . Pfizer (Australia) SODIUM CHLORIDE 0.9% irrigation solution ampoule

Product Type	Single Medicine Product	**Effective Date**	16/02/2021

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

INDICATIONS AS PER 11 JUNE 2002: Indicated during surgical procedures where isotonic irrigation is required e.g. irrigation of body cavities, tissues or wounds, indwelling urethral catheters and surgical drainage tubes. Dilution of medications prior to use in accordance with the product information for the medication being diluted e.g. to dilute inhalation solutions prior to nebulisation.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Ampoule	LDPE	3 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
30 x 30mL "Steritube" ampoules	Not scheduled. Not considered by committee

Components

1 . Pfizer (Australia) SODIUM CHLORIDE 0.9% irrigation solution ampoule

Dosage Form	Solution, irrigation
Route of Administration	Topical
Visual Identification	A clear, colourless liquid free from visible particles.

Active Ingredients

sodium chloride	**270 mg**

Other Ingredients (Excipients)

hydrochloric acid
sodium hydroxide
water for injections