Public Summary

Summary for ARTG Entry:	142370	INFANRIX diphtheria toxoid / pertactin / pertussis filamentous haemagglutinin / pertussis toxoid / tetanus toxoid 0.5mL injection syringe

ARTG entry for	Medicine Registered
Sponsor	GlaxoSmithKline Australia Pty Ltd
Postal Address	PO Box 18095, Melbourne, VIC, 8003 Australia
ARTG Start Date	2/12/2009
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 . INFANRIX diphtheria toxoid / pertactin / pertussis filamentous haemagglutinin / pertussis toxoid / tetanus toxoid 0.5mL injection syringe

Product Type	Single Medicine Product	**Effective Date**	8/04/2024

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

Infanrix is indicated as fourth and fifth dose for children from 15 months of age up to and including 6 years of age who have been immunised previously with three or four doses of diphtheria, tetanus and pertussis (whole-cell) vaccine. INDICATIONS AS OF 8TH JANUARY 1997 - Infanrix (DTPa) is indicated for active primary immunisation against diphtheria, tetanus and pertussis when commenced between 2 months and 12 months of age. Infanrix (DTPa) is also indicated as fourth and fifth dose for children from 15 months of age up to and including 6 years of age who have been immunised previously with three or four doses of diphtheria,tetanus and pertussis (whole-cell or acellular) vaccine.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Syringe	Glass Type I Clear	3 Years	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
10 x syringe	(S4) Prescription Only Medicine
0.5mL x syringe x 1	(S4) Prescription Only Medicine
0.5mL x syringe with needle (Aust L 19009) x 1	(S4) Prescription Only Medicine

Components

1 . INFANRIX diphtheria toxoid / pertactin / pertussis filamentous haemagglutinin / pertussis toxoid / tetanus toxoid 0.5 mL injection syringe

Dosage Form	Injection, suspension
Route of Administration	Intramuscular
Visual Identification	White turbid suspension

Active Ingredients

Diphtheria toxoid	**60 IU/mL**
Pertactin	**16 microgram/mL**
Pertussis filamentous haemagglutinin	**50 microgram/mL**
Pertussis toxoid	**50 microgram/mL**
Tetanus toxoid	**80 IU/mL**

Other Ingredients (Excipients)

aluminium hydroxide hydrate
sodium chloride
water for injections

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