Public Summary

Summary for ARTG Entry:	385069 QUADRACEL 0.5mL injection prefilled syringe
ARTG entry for	Medicine Registered
Sponsor	Sanofi-Aventis Australia Pty Ltd
Postal Address	Locked Bag 2227, NORTH RYDE BC, NSW, 1670 Australia
ARTG Start Date	24/05/2022
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 . QUADRACEL 0.5mL injection prefilled syringe

Product Type	Single Medicine Product	**Effective Date**	15/03/2024

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

Quadracel is indicated for primary immunisation of children from the age of 2 months to 12 months against diphtheria, tetanus, pertussis, and poliomyelitis.,Quadracel is also indicated for the fourth dose for children from 15 months to six years of age who have been immunised previously with three doses of diphtheria, tetanus, pertussis and polio vaccines.

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	36 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted	Do not Freeze

flow insert

Pack Size/Poison information

Pack Size	Poison Schedule
10 monodose prefilled syringes	(S4) Prescription Only Medicine

Components

1 . Medicine Component

Dosage Form	Injection, suspension
Route of Administration	Intramuscular
Visual Identification	Sterile, uniform, cloudy, white to off-white suspension

Active Ingredients

Diphtheria toxoid	**30 IU**
Pertactin	**3 microgram**
Pertussis filamentous haemagglutinin	**20 microgram**
Pertussis fimbriae 2 + 3	**5 microgram**
Pertussis toxoid	**20 microgram**
Poliovirus	**29 DAgU**
Poliovirus	**26 DAgU**
Poliovirus	**7 DAgU**
Tetanus toxoid	**40 IU**

Other Ingredients (Excipients)

aluminium phosphate
bovine serum albumin
formaldehyde
glutaral
neomycin
phenoxyethanol
polymyxin B sulfate
polysorbate 80
water for injections

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