



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 163897 PANVAX H1N1 VACCINE, H1N1 pandemic influenza vaccine (split-virion, inactivated) 10mL multi-dose injection vial

ARTG entry for Medicine Registered
Sponsor CSL Innovation Pty Ltd
Postal Address 45 Poplar Road, PARKVILLE, VIC, 3052
 Australia
ARTG Start Date 18/09/2009
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 . PANVAX H1N1 VACCINE, H1N1 pandemic influenza vaccine (split-virion, inactivated) 10mL multi-dose injection vial

Product Type	Single Medicine Product	Effective Date	5/03/2010
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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

For active immunisation to prevent influenza disease caused by the influenza A (H1N1) virus, in persons from 6 months of age.

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	1 Years	Store at 2 to 8 degrees Celsius	Not recorded	Protect from Light Do not Freeze Refrigerate

Pack Size/Poison information

Pack Size	Poison Schedule
50 x 10mL vial	(S4) Prescription Only Medicine
10 x 10mL vial	(S4) Prescription Only Medicine

Components

1 . inactivated split-virion monovalent influenza vaccine 10 mL multi-doswe vial

Dosage Form Injection, suspension

Route of Administration Intramuscular

Visual Identification

Active Ingredients

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Influenza virus haemagglutinin

15 microgram

Other Ingredients (Excipients)

calcium chloride dihydrate
dibasic sodium phosphate
monobasic potassium phosphate
monobasic sodium phosphate
potassium chloride
sodium chloride
thiomersal

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