



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 Limited	
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	Refrigerate Do not Freeze Protect from Light

Pack Size/Poison information

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

Influenza virus haemagglutinin 15 microgram

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