

## 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
--------------	-------------------------	----------------	-----------

### Warnings

See Product Information and Consumer Medicine Information for this product

### Standard Indications

### Specific Indications

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

### 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**