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	Do not Freeze, Refrigerate, Protect from Light

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

Influenza virus haemagglutinin	**15 microgram**

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