Public Summary

Summary for ARTG Entry: 68713 ERVEVAX rubella vaccine 1000 CCID50 powder for injection single dose vial

ARTG entry for	Medicine Registered
Sponsor	GlaxoSmithKline Australia Pty Ltd
Postal Address	PO Box 168, BORONIA, VIC, 3155 Australia
ARTG Start Date	04/05/99

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. ERVEVAX rubella vaccine 1000 CCID50 powder for injection single dose vial

Product Type Single Medicine Product **Effective date** 18/11/2008

Warnings

No Warnings included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Active immunisation against rubella. Studies with RA27/3 vaccines have shown that an antibody response can be obtained in individuals aged 12 months or order, but vaccination before that age may fail due to the possible persistence of maternal antibodies. However, according to the current guidelines of the National Health and Medical research Council, females only should be immunised, and at the age of 10 to 14 years. Susceptible females of childbearing potential, as shown by serological testing, should also be considered for vaccination if they are not pregnant and agree to prevent pregnancy for 3 months following vaccination. The immediate postpartum period is a suitable time for vaccination of such subjects, and breastfeeding is not a contraindication to rubella vaccination. Previous administration of human anti-Rh(D) immunoglobulin or other blood products in the postpartum period is also not a contraindication to vaccination but in such case it is advisable to ascertain the seroconversion has occurred by testing a serum sample obtained about 3 months after vaccination. A history of rubella is usually not reliable enough to exclude subjects from immunisation.

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Not recorded	2 Years	Store at 2 to 8 degrees Celsius	Not recorded	Refrigerate

Pack Size/Poison information

Pack Size	Poison Schedule
10 x 1 dose vials	(S4) Prescription Only Medicine
25 x 1 dose vials	(S4) Prescription Only Medicine

Components

1. Medicine Component

Dosage Form	Injection, powder for
Route of Administration	Subcutaneous
Visual Identification	Pink powder pellet.

Active Ingredients

Rubella virus	1000 CCID50

Public Summary