

**เอกสารกำกับยาภาษาอังกฤษ**  
**RUBELLA VACCINE, Live, Attenuated (Freeze-Dried)**  
**Vaccinum Rubeolae vivum**

**Description**

Rubella Vaccine, Live, Attenuated (Freeze-Dried) is prepared using Wistar RA 27/3 strain Rubella vaccine virus. This vaccine virus is propagated on human diploid cells (HDC). The vaccine is lyophilized and is provided with diluent. The product has the appearance of a yellowish white dry cake. The vaccine meets the requirements of WHO when tested by the methods outlined in WHO, TRS 840 (1994).

**Potency**

Each single human dose when reconstituted in a volume of 0.5 ml. contains not less than 1000 CCID<sub>50</sub> of live virus particles. Stability data has shown that the vaccine retains the potency of 1000 CCID<sub>50</sub> per dose after 1 week at 37°C.

**Indications**

Rubella vaccine is indicated for:

- 1) Immunization against Rubella in persons from 12 months of age to puberty
- 2) Vaccination of adolescent and adult males may be a useful procedure in preventing or controlling outbreaks of rubella in circumscribed population groups.
- 3) Non pregnant adolescent and adult females:

Immunization of susceptible non pregnant adolescent and adult females of child bearing age with live attenuated Rubella virus vaccine is indicated if certain precautions are observed. Vaccinating susceptible postpubertal females confers individual protection against subsequently acquiring rubella infection during pregnancy, which in turn prevents infections of foetus and consequent congenital rubella injury. Women of child bearing age should be advised not to become pregnant for two months after vaccination.

- 4) Postpartum Woman:

It has been found convenient in many instances to vaccinate rubella susceptible women in the immediate postpartum period.

- 5) Revaccination:

Children first vaccinated when younger than 12 months of age should be revaccinated. Based on available evidence, there is no reason to routinely revaccinate persons who were vaccinated originally when 12 months of age or older. However, persons should be revaccinated if there is evidence to suggest that initial immunization was ineffective.

Rubella vaccine can be safely and effectively given simultaneously with DTP, DT, TT, BCG and Polio vaccine (OPV and IPV), Hepatitis B and yellow fever vaccine.

## **Application and Dosage**

The vaccine should be reconstituted with the diluent supplied (Sterile water for injection) using a sterile syringe and needle. With gentle shaking the dried cake is easily dissolved. After reconstitution the vaccine should be used immediately. A single dose of 0.5 ml should be administered by deep subcutaneous injection into the upper arm. If the vaccine is not used immediately then it should be stored in the dark between 2 and 8°C for no longer than 8 hours.

## **Reactions**

Burning and/or stinging of short duration at the injection have been reported.

Mild local reactions such as induration urticaria rash, malaise, sore throat, fever, headache dizziness, nausea, vomiting, diarrhoea, regional lymphadenopathy, polyneuritis and arthralgia and/or arthritis may occur. Local pain, wheal and flare, induration and erythema may occur at the site of injection. Reactions are usually mild and transient, cough and rhinitis have also been reported. Moderate fever (101-102.9°F) occurs occasionally and high fever over 103°F occurs less commonly.

## **Contraindications and Warnings**

There are few contraindications to the administration of rubella vaccine. Individuals receiving corticosteroids, other immunosuppressive drugs or undergoing radio-therapy may not develop an optimal immune response. The vaccine should not be given in acute infectious diseases, leukaemia, severe anaemia and other severe diseases of the blood system, severe impairment of the renal function, decompensated heart diseases, following administration of gammaglobulin or blood transfusions. Low grade fever, mild respiratory infection or diarrhoea and other minor illness should not be considered as contraindication. It is particularly important to immunize children with malnutrition. Since the effect of the live rubella vaccine on the fetus is not known, it is also contraindicated in pregnancy.

## **HIV Infection**

Rubella vaccine may be used in children with known or suspected HIV Infection. Although the data are limited and further studies are being encouraged, there is no evidence to date of any increased rate of adverse reactions using this or other rubella vaccines in symptomatic or asymptomatic HIV-infected children. Rubella vaccine should be avoided in other cell-mediated immune deficiency states.

**DO NOT ADMINISTER THE VACCINE DURING PREGNANCY, CAUTION VACCINEES NOT TO CONCEIVE FOR THE TWO MONTH PERIOD FOLLOWING VACCINATION.**

## **Storage**

The vaccine should be stored in the dark at a temperature between 2-8°C. For long term storage a temperature of -20°C is recommended for the vaccine. The diluent should not be frozen, but should be kept cool.

**Shelf life**

24 months from date of last satisfactory potency test, if stored in a dark place at a temperature between 2-8° C.

**Presentation**

1 Dose Vial plus diluent

2 Dose Vial plus diluent

5 Dose Vial plus diluent

10 Dose Vial plus diluent

**MOST IMPORTANT**

Please ensure that the vaccine is administered by subcutaneous route only. In rare cases anaphylactic shock may occur in susceptible patient and for such emergency please keep handy 1:1000 adrenaline injection ready to be injected intramuscularly. This will help in tackling the anaphylactic shock/reaction effectively.

**Manufactured by:**

SERUM INSTITUTE OF INDIA PVT. LTD.  
212/2, Hadapsar, Pune-411 028, INDIA.  
Protection from Birth Onwards.

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