SUMMARY PRODUCT CHARECTERISTICS

Rubella Vaccine (LIVE) I.P Freeze Dried (M-VAC)

DESCRIPTION	Rubella Vaccine Live, attenuated (R-VACTM) (Lyophilised) 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 BP and W.H.O. when tested by the methods outlined in BP and WHO TRS 840 (1994).
POTENCY	Each single human dose when reconstituted in a volume of 0.5 ml. contains not less than 1000 CCID50 of live virus particles. Stability data has shown that the vaccine retains the potency of 1000 CCID50 per dose after 1 week at 37°C.
THERAPEUTIC INDICATIONS	Rubella vaccine (R-VACTM) 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 28 days 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.
DOSAGE & METHOD OF ADMINISTRATION	The vaccine should be reconstituted only 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 0.5ml should be administered by deep subcutaneous injection into the upper arm.
CONTRAINDICATONS	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 tranfusions. 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. Rubella vaccine should not be administered to women known to be pregnant. Because a risk to the fetus from administration of these Live virus vaccines cannot be excluded for theoretical reasons. Women should be counseled to

	avoid becoming pregnant for 28 days after vaccination with Rubella vaccine.
SPECIAL WARNINGS & PRECAUTION FOR USE	Please ensure that the vaccine is administered by subcutaneous route only. In a rare case 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.
INTERACTION WITH OTHER MEDICAL PRODUCTS & OTHER FORM OF INTERACTION	Due to the risk of inactivation, rubella vaccines should not be given within 6 weeks, and if it is possible 3 months, after an injection of immunoglobulins or blood product containing immunoglobulins (blood, plasma). For the same reason, immunoglobulins should not be administered within two weeks after the vaccination. Tuberculin positive individuals may transitionally become tuberculin negative after vaccination.
PREGNANCY & LACTATION	Contraindicated during pregnancy.
UNDESIRABLE EFFECTS	Burning and / or stinging of short duration at the injection site 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.
STORAGE OF VACCINES	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.
PRESENTATION	1 dose vial plus diluent (0.5ml) 2 dose vial plus diluent (1ml) 5 dose vial plus diluent (2.5ml) 10 dose vial plus diluent (5ml)
MARKETING AUTHORIZATON HOLDER	Serum Institute of India Ltd
PRODUCT REGISTRATION NUMBER	BHU-DRA/B02726 BHU-DRA/B02727 BHU-DRA/B02728 BHU-DRA/B02729