SUMMARY PRODUCT CHARECTERISTICS

Measles and Rubella Vaccine Live attenuated (2 dose vial)

DESCRIPTION	The vaccine is prepared from the live, attenuated strains of Edmonston-Zagreb measles virus and Wistar RA 27/3 rubella virus. Both measles and rubella viruses are propagated on human diploid cells (DHDC). The vaccine is lyophilized and provided with diluents. The product has appearance of yellowish-white dry cake.
POTENCY	Each single human dose when reconstituted in a volume of 0.5 ml contains not less than $1000CCID_{50}$ of the measles virus and 1000 $CCID_{50}$ of rubella virus.
THERAPEUTIC INDICATIONS	For active immunization against measles and rubella in infants, children, adolescents and young adults at risk. Immunization of susceptible non-pregnant adolescent and adult females is indicated if certain precautions are observed. The vaccine can be safely and effectively given simultaneously with DTP, Td, BCG, Polio vaccine(OPV and IPV), Haemophilus influenza type b, Hepatitis B, Yellow fever vaccine and vitamin A supplementation.
DOSAGE & METHOD OF ADMINISTRATION	The vaccine should be reconstituted only with the entire diluents supplied (Sterile water for injections) 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 anterolateral aspect of upper thigh in toddler and upper arm in older children. If the vaccine is not used immediately then it should be stored in the dark at 2-8^{o}C for no longer than 6 hours. Any opened container remaining at the end of a session (within six hours of reconstitution) should be discarded. The diluent supplied is specially designed for use with the vaccine. Only this diluent must be used to reconstitute the vaccine. Do not use diluents from other types of vaccine or for MR vaccine from other manufacturers. Water for Injections must NOT be used for this purpose. Using incorrect diluents may result in damage to the vaccine and/ or serious reactions to those receiving the vaccine. Diluent must not be frozen but should be kept cool. CLOSE ATTENTION SHOULD BE PAID TO THE CONTRAINDICATIONS LISTED The diluents and reconstituted vaccine should be inspected visually for any foreign particulate matter and/ or variation of physical aspects prior to administration. In the event of either being observed, discard the diluents or reconstituted vaccine.
CONTRAINDICATONS	Individuals receiving corticosteroids, other immune-suppressive drugs or undergoing radio-therapy may not develop an optimal immune response. The vaccine may contain traces of neomycin. Anaphylactic or anaphylactoid reactions to neomycin, history of anaphylactic or anaphylactoid reactions are absolute contraindications. Low grade fever, mild respiratory infections or diarrhea, and other minor illness should not be considered as contraindication. It is particularly important to immunize children with malnutrition. IMMUNE DEFICIENCY Measles and Rubella vaccine may be used in children with known or suspected HIV infection. The vaccine is contraindicated in persons who are severely immunocompromised as a result of congenital disease, HIV infection, advanced leukaemia or lymphoma, serious malignant disease, or treatment with high-dose steroids, alkylating agents or anti-metabolites, or in persons who are receiving immunosuppressive therapeutic radiation.
SPECIAL WARNINGS & PRECAUTION FOR USE	The vaccine should not be given in febrile states, pregnancy, 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 or to subjects with potential allergies to vaccine components. There are extremely rare reports of hypersensitivity reactions with MMR vaccines in individuals who are allergic to cow's milk. Such

	individuals should not receive the vaccine.
INTERACTION WITH OTHER MEDICAL PRODUCTS & OTHER FORM OF INTERACTION	Due to the risk of inactivation, the rubella vaccine should not be given within 6 weeks, and if it is possible the 3 months, after an injection of immunoglobulin or blood product containing immunoglobulins(blood, plasma). For the same reasons, immunoglobulins should not be administered within two weeks after the vaccination. Tuberculin positive individuals may traditionally become tuberculin negative vaccination.
PREGNANCY & LACTATION	MR Vaccine should not be administered in pregnant women because of theoretical but never demonstrated teratogenic risk. Inadvertent receipt of MR vaccine during pregnancy is not an indication for an abortion. Since MR vaccine is recommended in adults, if pregnancy is planned, then an interval of one month should be observed after MR vaccination. No CRS have been reported in any pregnant women who inadvertently received rubella-containing vaccine in early pregnancy.
UNDESIRABLE EFFECTS	The type and rate of severe adverse reactions do not differ significantly from the measles and rubella vaccine reactions described separately. The measles vaccine may cause within 24 hours of vaccination mild pain and tenderness at the injection site. In most cases, they spontaneously resolve within two to three days without further medical attention. A mild fever can occur in 5-15% of vaccines 7 to 12 days after vaccination and last for 1-2 days. Rash occurs in approximately 2% of recipients, usually starting 7-10 days after vaccination and lasting 2 days. The mild side effects occur less frequently after the second dose of a measles-containing vaccine and tend to occur only in person not protected by the first dose. Encephalitis has been reported following measles vaccination at a frequency of approximately one case per million doses administered although a causal link is not proven. The rubella component may commonly result in joint symptoms manifested as arthralgias (25%) and arthritis (10%) among adolescent and adult females that usually last from a few days to 2 weeks. However, such adverse reactions are very rare in children and in men receiving MR vaccine (0%-3%). Symptoms typically begin 1-3 weeks after vaccination and last 1 day to 2 weeks. These transient reactions seem to occur in non-immunes only, for whom the vaccine is important. Low-grade fever and rash, lymphadenopathy, myalgia and paraesthesiae are commonly reported. Thrombocytopenia is rare and has been reported in less than 1 case per 30 000 doses administered. Anaphylactic reactions are also rare. In susceptible individuals the vaccine may very rarely cause allergic reactions like urticaria, pruritis and allergic rash within 24 hours of vaccination. Clinical experience has exceptionally recorded isolated reactions involving the CNS. These more serious reactions have however, not been directly linked to vaccination.
STORAGE OF VACCINES	IT IS IMPORTANT TO PROTECT BOTH THE FREEZE-DRIED AND RECONSTITUTED VACCINE FROM THE LIGHT. The vaccine should be stored in the dark at a temperature between 2-8ºC. For long term storage a temperature of -20ºC is recommended for the freeze-dried vaccine. The diluent should not be frozen, but should be kept cool.
PRESENTATION	1 Dose vial plus diluent (0.5 ml) 2 Dose vial plus diluent (1 ml) 5 Dose vial plus diluent (2.5 ml) 10 Dose vial plus diluent (5 ml)
MARKETING AUTHORIZATON HOLDER	Serum Institute of India.

PRODUCT REGISTRATION NUMBER	BHU-DRA/B02699 BHU-DRA/B02700