SUMMARY PRODUCT CHARECTERISTICS

Measles, Mumps and Rubella Vaccine Live Attenuated (MMR Vaccine)

DESCRIPTION	The vaccine is prepared from the live attenuated strains of Edmonston-Zagreb measles virus, Leningrad-Zagreb (L-Z) mumps virus and wister RA 27/3 rubella virus. The measles and rubella viruses are propagated on human diploid cells (HDC) and mumps virus is grown on chick fibroblast from SPF eggs (specific pathogen free eggs). The vaccine freeze-dried and is provided with diluent. The product has appearance of 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 the volume of 0.5ml contains not less than 1000 $CCID_{50}$ of measles virus, 5000 $CCID_{50}$ of mumps virus and 1000 $CCID_{50}$ of Rubella virus. In addition, the freeze-dried vaccine when stored at 37°C for 7 days shows no loss in potency (less than 1.0 $\log_{10}$ loss in virus titres).
THERAPEUTIC INDICATIONS	For active immunization against measles, mumps and rubella in children from 12 months to 10 years of age. Second dose of MMR is usually advocated any time before the age of 6 years (elementary school entry 4-6 years). In children above 10 years, adolescents and adults, measles rubella (MR) is recommended. Revaccination may seroconvert primary failures of boost antibody titres of previously vaccinated individuals whose titers have declined. The advisory committee on immunization practice (ACIP) recommends administration of first dose of MMR at 12-15 months of age and administration of the second dose of MMR at 4-6 years of age. The vaccines can be safely and effectively given simultaneously with DTP, DT, TT, Td, BCG, Polio vaccine (OPV and IPV), H. influenzae type b, Hepatitis B, or yellow fever vaccine or vitamin A supplementation.
DOSAGE & METHOD OF ADMINISTRATION	The vaccine should be reconstituted only with the entire diluent 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 toddlers and upper arm in older children. If the vaccine is not used immediately then it should be stored in the dark at 2-8°C for no longer than 6 hours. Any opened container remaining at the end of a session (within 6 hours of reconstitution) should be discarded. The vaccines vial monitor, for this vaccines are usually attached to the vial cap and should be discarded when the vaccines is being reconstituted. The diluent supplied is specially designed for use with the vaccine. Only these diluents must be used to reconstitute the vaccine. Do not use diluents from other type of vaccine or for MMR vaccine from other manufacturers. Water for injection must NOT be used for this purpose. Using an incorrect diluents may result in damage to the vaccine and/or serious reaction to those receiving the vaccine. Diluent must not be frozen but should be kept cool. CLOSE ATTENTION SHOULD BE PAID TO THE CONTRINDICATIONS LISTED. The diluents and reconstituted vaccine should be inspected usually for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, discard diluent or reconstituted vaccine.
CONTRAINDICATONS	This vaccine should not be given in febrile states, pregnancy, acute infectious disease, leukemia, severe anemia and other severe diseases of blood system, severe impairment of renal function, decompensated heart diseases.

	History of anaphylactic or anaphylactoid reaction to eggs (hypersensitivity to eggs), are absolute contraindications.
SPECIAL WARNINGS & PRECAUTION FOR USE	Individuals receiving corticosteroids, other immunosuppressant drugs or undergoing radiotherapy may not develop an optimal immune responds. Low grade fever, mild respiratory infections or diarrhea, and other minor illness should not be considered as contraindication. If pregnancy is planned, than an interval of one month should be observed after MR vaccination.
INTERACTION WITH OTHER MEDICINAL PRODUCTS & OTHER FORM OF INTERACTION	Due to risk of inactivation the MMR vaccines should not be given within the 6 weeks, and if it is possible the 3 months, after an injection of immunoglobulin or blood product containing immunoglobulin (blood), (plasma). For the same reason, immunoglobulin should not be administered within the 2 weeks after the vaccination. Tuberculin positive individuals may transitionally become tuberculin negative after vaccination.
UNDESIRABLE EFFECTS	During post-marketing surveillance, the following reactions have been reported in temporal association with MMR vaccination: **Infections and infestations** Meningitis **Blood and lymphatic system disorders** Thrombocytopenia, thrombocytopenic purpura **Immune system disorders** Anaphylactic reactions **Nervous system disorders** Transverse myelitis, Guillain Barré syndrome, peripheral neuritis, encephalitis **Skin and subcutaneous tissue disorders** Erythema multiforme **Musculoskeletal and connective tissue disorders** Arthralgia, arthritis **General disorders and administration site conditions** Kawasaki syndrome. As in natural rubella infection, arthralgia, or in isolated cases, chronic arthritis as well as myalgia, exanthema and swollen lymph nodes may occur 2 - 4 weeks after administration of live rubella vaccines. The incidence of joint reactions increases with the age of the vaccinee. Cases of exudative arthritis are extremely rare. In rare cases a mumps-like condition with an abbreviated incubation period cannot be ruled out. In isolated cases, a transient, painful swelling of the testicles had been reported after combined mumps, measles, rubella vaccination. Accidental intravascular administration may give rise to severe reactions or even shock. Immediate measures depend on the severity of the reaction. In comparative studies with other measles, mumps and rubella vaccines, the incidences of local pain, redness and swelling reported with MMR were low, while the incidences of other adverse reactions were similar. Encephalitis has been reported with a frequency below 1 per 10 million doses. The risk of encephalitis following administration of the vaccine is far below the risk of encephalitis caused by natural diseases (measles: 1 in 1000 to 2000 cases; rubella: approximately 1 in 6000 cases). In rare cases a measles-like syndrome has been reported following vaccination with MMR
STORAGE OF VACCINES	It is important to protect both the freeze-dried and reconstituted vaccine from the light. The vaccine should be stored in a dry, dark place at a temperature between 2-8°C. For long term storage a temperature of -20°C is recommended for the freeze dried vaccine. The diluent should not be frozen but should be kept cool.

PRESENTATION	1 dose vial + diluent (0.5ml). 2 dose vial + diluent (1ml). 5 dose vial + diluent (2.5ml). 10 dose vial + diluent (5ml).
MARKETING AUTHORIZATON HOLDER	Serum Institute of India, Ltd.
PRODUCT REGISTRATION NUMBER	BHU-DRA/B02687, BHU-DRA/B02688, BHU-DRA/B02689, BHU-DRA/B02690