



SUMMARY PRODUCT CHARECTERISTICS

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

DESCRIPTION	M-VAC (Measles Vaccine (Live) I.P.) freeze-dried contains live attenuated measles virus (Edmonston Zagreb Strain) propagated on Human Diploid Cells (HDC). Each dose of 0.5 ml contains not less than 1000 CCID 50 of Measles virus on reconstitution with the diluent (Sterile Water for Injections) provided. The product has the appearance of a yellowish white dry cake.
POTENCY	Each dose of 0.5 ml contains not less than 1000 CCID 50 of Measles virus on reconstitution with the diluents. Stability data has shown that the freeze dried vaccine retains potency of 1000 CCID 50 per dose after 1 week at 37 degree Celsius.
THERAPEUTIC INDICATIONS	M-VAC is indicated for immunisation of all susceptible children against measles. It is recommended to be given to children at 9 months of age, or as soon as thereafter, to protect against measles in early life. Immunisation against measles is particularly important for institutionalized children and for children who may be malnourished or subject to chronic diseases such as heart disease, cystic fibrosis, asthma, tuberculosis or other chronic pulmonary disorders.
DOSAGE & METHOD OF ADMINISTRATION	Reconstitute the freeze dried vaccine by adding the entire contents of the diluent (Sterile Water for Injections) supplied to the single-dose vial by using sterile disposable 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. The diluent 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 diluent or reconstituted vaccine. The reconstituted vaccine must be used immediately otherwise it should be discarded.
CONTRAINDICATIONS	Febrile state Acute infectious diseases Severe diseases of the hematopoietic system Severe impairment of the renal function Decompensated heart diseases States of reduced immunity, either congenital or therapeutically acquired through irradiation and use of corticosteroid or cytotoxic drugs States of reduced immunity, following the transplantation of an organ Diseases and disorders of the central nervous system Within three months following the administration of gammaglobulin or blood-transfusion, Within six months following exchange transfusion Pregnancy.
SPECIAL WARNINGS & PRECAUTION FOR USE	Please ensure that the vaccine is administered by subcutaneous route only. In rare cases anaphylactic shock may occur in susceptible individual and for such emergency please keep handy 1:1000 adrenaline injection ready to be injected intramuscularly or subcutaneously. Single paediatric dose should not exceed 0.5mg (0.5ml). This will help in tackling the anaphylactic shock/reaction effectively.
INTERACTION WITH OTHER MEDICAL	Due to the risk of inactivation, measles vaccines should not be given within 6 weeks, and if it is possible 3 months, after an injection of immunoglobulins or blood product

PRODUCTS & OTHER FORM OF INTERACTION	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	Some mild reactions may occur such as marginal temperature rise in 5% to 6% of the vaccinated children, mild rash in 1% to 2% children, occasionally mild rash and slight gastric disorders or short-lived rhinopharyngitis. Fever or rash, or both, generally appear between the 5th and the 12th day after vaccination and last for one to two days.
STORAGE OF VACCINES	M-VAC should be stored between +2°C and +8°C. Protect from light. Diluent should not be frozen and should be stored in a clean place away from heat and sunlight.
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/B02722 BHU-DRA/B02723 BHU-DRA/B02724 BHU-DRA/B02725