For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

MEASLES VACCINE (LIVE) I.P.

M-VAC™

(Freeze-Dried)

Live, attenuated Measles virus (Edmonston - Zagreb Strain) propagated on Human Diploid Cells (HDC).

Composition

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.

Indication

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.

Directions for Use

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.

Reactions

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.

Contraindications

It is particularly important to immunize children suffering from malnutrition. Low-grade fever, mild respiratory infections or diarrhoea, and other minor illness should not be considered as contraindications to immunisation.

Only the following should be regarded as contraindications :

1. Febrile state,
2. Acute infectious diseases,
3. Severe diseases of the hematopoietic system,
4. Severe impairment of the renal function,
5. Decompensated heart diseases,
6. States of reduced immunity, either congenital or therapeutically acquired through irradiation and use of corticosteroid or cytostatic drugs,
7. States of reduced immunity, following the transplantation of an organ,
8. Diseases and disorders of the central nervous system,
9. Within three months following the administration of gammaglobulin or blood-transfusion,
10. Within six months following exchange transfusion,
11. Pregnancy.

Advantages

M-VAC can also be given to the patients who are allergic to egg protein or neomycin because it is prepared on Human Diploid Cells and does not contain neomycin.

Storage

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

M-VAC is presented as freeze-dried vaccine
1 Dose x 10 vials pack plus diluent (0.5ml Sterile Water for Injections I.P.) and sterile disposable syringe and needle supplied separately.
M-VAC fulfils the relevant requirements of W.H.O.

MOST IMPORTANT WARNING

1. 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. For treatment of severe anaphylaxis the initial dose of adrenaline is 0.1-0.5 mg (0.1-0.5ml of 1:1000 injection) given s/c or i/m. Single dose should not exceed 1 mg (1ml). For infants and children the recommended dose of adrenaline is 0.01mg/kg (0.01ml/kg of 1:1000 injection). Single paediatric dose should not exceed 0.5mg (0.5ml). This will help in tackling the anaphylactic shock/reaction effectively

2. The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be lifesaving. It should be used at the first suspicion of anaphylaxis. As with the use of all vaccines the vaccinees should remain under observation for not less than 30 minutes for possibility of occurrence of rapid allergic reactions.Efcorlin hydrochloride and antihistaminics should also be available in addition to supportive measures such as oxygen inhalation.

FREEZE-DRIED PREPARATIONS

Instructions for use

1) Draw the diluent from the ampoule into a syringe, pierce the bung of the vial with the needle and gently inject the diluent into the vial.

2) Detach the syringe, leaving the needle in vial bung. After 15 seconds remove the needle.

3) Rotate the vial gently between your palms till the material dissolves. Avoid shaking the vial as this would cause frothing.

4) Withdraw the reconstituted solution into the syringe, now ready for administration.

Manufactured by:
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Protection from birth onwards

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