

## เอกสารกำกับยาภาษาอังกฤษ

### **MEASLES VACCINE, Live, Attenuated (Freeze-Dried)**

#### **Vaccinum morbillorum vivum**

#### **Description**

Measles vaccine, live, attenuated (Freeze-dried) is prepared from the Edmonston strain measles virus which has been further attenuated by twenty two passages on human diploid cells (HDC) and is known as the Edmonston-Zagreb strain. The virus in the final vaccine is also propagated on HDC and is from the second cell culture passage from the seed virus. 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 WHO when tested by the methods outlined in WHO, 840 (1994).

#### **Potency**

Each single human dose when reconstituted in a volume of 0.5 ml. contains not less than 1000 CCID<sub>50</sub> of live virus particles. Stability data has shown that the vaccine retains the potency of 1000 CCID<sub>50</sub> per dose after 1 week at 37°C.

#### **Indications**

For active immunization against measles. A single dose of measles vaccine is sufficient to provide prolonged immunity to infection. In countries where the incidence and mortality from measles is high in the first year of life, the recommended age for immunization against measles is as soon as possible after 9 months of age (270 days). Countries where measles is less of a problem may decide on a later date for immunization. The vaccine is also recommended for use in children and adolescents with no evidence of vaccination or measles infection. The vaccine can also be administered to children and adolescents who have been vaccinated before or have had Measles infection earlier. Measles vaccine can be safely and effectively given simultaneously with DPT, DT, TT, BCG and Polio vaccine (OPV and IPV), Hepatitis B and Yellow Fever Vaccine.

#### **Application and Dosage**

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 0.5 ml should be administered by deep subcutaneous injection into the upper arm. If the vaccine is not used immediately then it should be stored in the dark at 2-8°C for no longer than 8 hours.

#### **Reactions**

Reactions are generally mild. A small increase in temperature (37.6°C) may occur in 5-6% of vaccines and a slight rash may be noticed in 1-2%.

## **Contraindications and Warnings**

There are few contraindications to the administration of measles 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 transfusions. Low grade fever, mild respiratory infections or diarrhoea, and other minor illness should not be considered as contraindications. It is particularly important to immunize children with malnutrition. Since the effect of the live measles vaccine on the fetus is not known, it is also contraindicated in pregnancy.

HIV Infection – Measles vaccine may be used in children with known or suspected HIV infection. Although the data are limited and further studies are being encouraged, there is no evidence to date of any increased rate of adverse reactions using this or other measles vaccines in symptomatic or asymptomatic HIV-infected children. Measles vaccine should be avoided in other cell-mediated immune deficiency states.

## **Storage**

**IT IS IMPORTANT TO PROTECT BOTH THE LYOPHILIZED AND RECONSTITUTED VACCINE FROM THE LIGHT.** The vaccine should be stored in the dark at 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.

## **Shelf life**

24 months from date of last satisfactory potency test, if stored in a dark place at a temperature between 2-8°C.

## **Presentation**

1 Dose Vial plus diluent

10 Dose Vial plus diluent

### **MOST IMPORTANT**

Please ensure that the vaccine is administered by subcutaneous route only. In rare cases 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.

## **Manufactured by:**

SERUM INSTITUTE OF INDIA PVT. LTD.

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Protection from Birth Onwards

## **Imported and Distributed by:**

MASU CO., LTD.