SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

Measles Vaccine Live, Attenuated (Freeze-Dried)
Diluent : Sterile Water For Injection I.P.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single human dose when reconstituted in a volume of 0.5 ml contains not less than 1000 $CCID_{50}$ of measles virus.

Diluent: It contains Water for Injections in bulk that has been distributed into suitable containers, closed and sterilized by heat in conditions. It is free from any added substances.

3. PHARMACEUTICAL FORM

Lyophilized Injection supplied with solvent for reconstitution

4. CLINICAL PARTICULARS

4.1 Therapeutic 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 at 9 months of age (270 days). In countries where infection occurs later in life (due to sustained high vaccine coverage), the age of immunisation can be moved to 12-15 months. 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 DTP, DT, TT, Td, BCG, Polio vaccine (OPV and IPV), Haemophilus influenzae type b, Hepatitis B, Yellow fever vaccine and vitamin A supplementation

4.2 Posology and 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 infants and upper arm in older children. If the vaccine is not used immediately then it should be stored in the dark at 2-8ºC 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 vaccine vial monitor, for this type of vaccine is attached to the vial cap and should be discarded when the vaccine is being reconstituted.

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 Measles vaccine from other manufacturers. Water for injections must NOT be used for this purpose. Using an incorrect diluent 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.

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.

4.3 Contraindications :

There are few contraindications to the administration of measles vaccine. Individuals receiving corticosteroids, other immuno-suppressive 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 disease, following administration of gammaglobulin or blood transfusions. Persons with a history of an anaphylactic reaction to any component of the vaccine should not be vaccinated. 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. 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.

IMMUNE DEFICIENCY:

Children with known or suspected HIV infection are at increased risk of severe measles and should be offered measles vaccine as early as possible.

Measles vaccine is contraindicated in persons who are severely immunocompromised as a result of a congenital immune disorder, 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.

4.4 Special Warnings and Special Precautions for Use :

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 (0.1-0.5 ml of 1:1000 injection) given s/c or i/m. Single dose should not exceed 1 mg (1 ml). For infants and children the recommended dose of adrenaline is 0.01 mg/kg (0.01ml/kg of 1:1000 injection). Single paediatric dose should not exceed 0.5 mg (0.5 ml). 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 vaccinee should remain under observation for not less than 30 minutes for possibility of occurrence of rapid allergic reactions. Hydrocortisone and antihistaminics should also be available in addition to supportive measures such as oxygen inhalation.

4.5 Interactions with other Medicinal Products :

Due to the risk of inactivation, the measles vaccine should not be given within the 6 weeks, and if it is possible the 3 months, after an injection of immunoglobulins or blood product containing immunoglobulins (blood, plasma).
For the same reason, immunoglobulins should not be administered within the two weeks after the vaccination.
Tuberculin positive individuals may transitionally become tuberculin negative after vaccination.

4.6 Pregnancy and Lactation :

Since the effect of the live measles vaccine on the fetus is not known, it is also contraindicated in pregnancy.

4.7 Effects on the ability to drive and use machines :

No studies on the effects on the ability to drive and use of machines have been performed.

4.8 Undesirable Effects :

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 vaccinees 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. In susceptible individuals the vaccine may very rarely cause allergic reactions like urticaria, pruritis and allergic rash within 24 hours of vaccination.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties :

5.1.1 Pharmacotherapeutic Group : (ATC Code)

JO7BD01

5.1.2 Mechanism of Action :

Measles vaccine stimulates active immunity to measles by inducing production of Measles-specific IgG antibodies.

5.1.3 Pharmacodynamic Effects :

Measles vaccine is used to provide active immunization against Measles.

5.1.4 Clinical Efficacy :

Clinical studies have shown that the Measles vaccine is highly immunogenic and generally well tolerated.

5.2 Pharmacokinetic Properties :

Not Applicable

5.3 Pre-clinical Safety Data :

No formal animal testing has been carried out for non-clinical assessment. However as a part of the quality control every batch of the vaccine is tested in mice and guinea pigs for general safety.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients :

- Partially Hydrolyzed Gelatin

- Sorbitol
- L-Histidine
- L-Alanine
- Tricine
- L-Arginine Hydrochloride
- Lactalbumin Hydrolysate
- Minimum Essential Medium

6.2 Incompatibilities :

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life :

30 months from date of last satisfactory potency test, if stored in a dark place at a temperature between 2-8ºC.
Diluent : 5 years

6.4 Special Precautions for Storage :

IT IS IMPORTANT TO PROTECT BOTH THE LYOPHILIZED AND RECONSTITUTED VACCINE FROM THE LIGHT. The vaccine should be stored in the dark at 2-8ºC. For long term storage a temperature of -20ºC is recommended for the lyophilised vaccine. Protect from light. The diluent should not be frozen, but should be kept cool.
Diluent : Store at room temperature not to be frozen.

6.5 Nature and Contents of container :

Lyophilized vaccine provided with diluent
1 dose vial plus ampoule containing 0.5 ml diluent
2 dose vial plus ampoule containing 1.0 ml diluent
5 dose vial plus ampoule containing 2.5 ml diluent
10 dose vial plus ampoule containing 5 ml diluent ml)

Vaccine Container : Amber coloured tubular type I vial, 50 mm in height with 13 mm slotted, Grey, Bromobutyl Rubber Stopper and 13 mm Flip off Aluminium Cap
Diluent Container : Type I Glass ampoule

6.6 Special precautions for disposal :

Any unused product or waste material should be disposed off in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER

Serum Institute of India Private Ltd.
212/2, Hadapsar
Pune 411 028
India

8. MARKETING AUTHORIZATION NUMBER

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9. DATE OF FIRST AUTHORIZATION / RENEWAL

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10. DATE OF REVISION OF TEXT