

**Registration No.:** 1C 1/59 (B)

**Importer / Manufacturer:** BioNet - Asia Co., Ltd. / PT. Bio Farma

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICAL PRODUCT

Measles Vaccine

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition	Dose
Volume	0.5 ml
Measles Virus strain CAM 70	not less than 1000 CCID <sub>50</sub>
Kanamycin sulphate	not more than 100 µgm
Erythromycin	not more than 30 µgm
Diluent	Water for injection (WFI)

### 3. PHARMACEUTICAL FORM

It is a live, attenuated virus vaccine. Each dose contains not less than 1,000 CCID<sub>50</sub> (cell culture infective doses 50%) of Measles virus strain CAM 70, prepared in SPF chicken embryo and not more than 100 mcg of kanamycin sulphate and 30 mcg of erythromycin. This vaccine is a freeze-dried product that must be reconstituted only with the sterile diluent provided separately for that purpose.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Prophylactic immunization against Measle.

#### 4.2 Posology and method of administration

##### *Immunization schedule*

In countries where the incidence and mortality from measles is high in the first year of life, the recommended age for vaccination against measles is at 9 months of age (270 days) or shortly after. In countries where infection occurs later in life (due to sustained high vaccination coverage), the age of vaccination can be moved to 12-15 months. It is recommended that all children have two (2) opportunities for measles immunization to reduce the number both of unvaccinated children and of those who are vaccinated but fail to respond to the vaccine (primary vaccination failure). Although generally administered at school entry (4-6 years of age), the second opportunity for measles immunization may be provided as early as one (1) month following the first dose through routine or supplemental immunization activities. Measles vaccine can be given safely and effectively simultaneously with DTP, Td, TT, BCG, Polio (OPV and IPV), Haemophilus influenzae type b, hepatitis B and yellow fever vaccine and vitamin A supplementation.

##### *Administration*

Measles vaccine is generally injected subcutaneously. The preferred site of injection is the upper arm. A sterile needle and sterile syringe must be used for each injection. Because of sensitivity to ultraviolet light the vaccine must be stored in the dark at +2°C and +8°C use within six (6) hours. Any opened vials remaining at the end of an immunization session (within six (6) 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 this vaccine. Only this diluent may be used to reconstitute the vaccine. Do not use diluent from other types of vaccine or for measles vaccine from other manufacturers. Using an incorrect diluent will result in damage to vaccine and/or serious reactions to those receiving the vaccine. Diluent must not be frozen but must be cooled between +2°C and +8°C before used for reconstitution.

#### **4.3 Contraindication**

There are few contraindications to the administration of measles vaccine. It is particularly important to immunize children with malnutrition. Person with a history of an anaphylactic reaction to any component of the vaccine should not be vaccinated. Low grade fever, mild respiratory infections or diarrhea, and other minor illnesses should not be considered as contraindications. Egg allergy is not considered to be a contraindication to vaccination. On theoretical grounds measles should also be avoided 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. The standard WHO recommendation for children at high risk of contracting is to immunize with measles vaccine at six (6) months of age, followed by an extra dose at nine (9) months. 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 a treatment with a high-dose of steroids, alkylating agents or anti-metabolites, or in persons who are receiving immunosuppressive therapeutic radiation.

#### **4.4 Special warnings and precautions for use**

See the topic of posology and method of administration

#### **4.5 Interaction with other medical products and forms of interaction**

N/A

#### **4.6 Pregnancy and lactation**

N/A

#### **4.7 Effects on the ability to drive and use machines**

N/A

#### **4.8 Undesirable effects**

Side effects following measles vaccination, alone or in fixed combination, are generally mild and transient. Slight pain and tenderness at the site of injection may occur within 24 hours of vaccination, sometime followed by mild fever and local lymphadenopathy. About 7-12 days after vaccination up to 5% of measles vaccine recipients may experience fever >39.4 °C for 1-2 days. A transient rash may occur in approximately 2% of vaccinees, usually starting 7-10 days following vaccination and lasting 2 days. Side effects, with the exception of anaphylactic reactions, are less likely to occur after receipt of a second dose of measles vaccine. Encephalitis has been reported following measles vaccination at a frequency of approximately one (1) case per one million doses administered although the causal link is not proven.

#### **4.9 Overdose**

N/A

## **5. PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

N/A

**5.2 Pharmacokinetic properties**

N/A

**5.3 Preclinical safety data**

N/A

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

D-sorbitol, Lactose monohydrate, Gelatin, L-cysteine HCl.H<sub>2</sub>O, Kanamycin sulphate, Erythromycin, Water for injection, Sterile water for injection

**6.2 Incompatibilities**

N/A

**6.3 Shelf life**

2 years

**6.4 Special precautions for storage**

Freeze-dried measles vaccine should be kept in the refrigerator between +2°C and +8°C until used. The vials of vaccine and the diluent should be transported together, but the diluent must not be frozen. Because of sensitivity to ultraviolet light the vaccine must be stored in the dark.

Freeze-dried measles vaccine could also be kept at -20 °C

**6.5 Nature and contents of container**

The vaccine comes in vials of 10 doses.

**6.6 Special precautions for disposal and other handling**

N/A

**7. MARKETING AUTHORISATION HOLDER**

BioNet - Asia Co.,Ltd. Bangkok, THAILAND

**8. MARKETING AUTHORISATION NUMBER(S)**

1C 1/59 (B)

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

February 17, 2016

**10. DATE OF REVISION OF THE TEXT**

May 9, 2018