

PACKAGE INSERT

MEASLES VACCINE Reg. No.: MAL29048ETTA

DESCRIPTION:

Measles vaccine, a sterile freeze-dried yellowish preparation of attenuated live Measles Virus (CAM-70 strain) which should be reconstituted only with a first sterile diluent provided separately for this purpose. The vaccine fulfils WHO Requirements. Each dose (0.5ml) contains not less than 1,000 CCID₅₀ of the attenuated live Measles Virus (CAM-70 strain); not more than 100 mcg of residual kanamycin sulphate and not more than 30 mcg of erythromycin.

After reconstitution, each dose (0.5ml) contains:-

Attenuated live Measles Virus (CAM-70 strain)	not less than 1,000 CCID ₅₀
G-Sortid [®]	2.0% w/v
Lactose Monohydrate	9.0% w/v
Gelatin	0.75% w/v
L-Cysteine HCl 100	0.2% w/v
Kanamycin Sulphate	not more than 100 mcg
Erythromycin	not more than 30 mcg
Water for Injection	q.s. ad 0.5 ml

NAME(S) AND STRENGTH (S) OF ACTIVE INGREDIENT(S)

After reconstitution, each dose of 0.5ml contains :-
- Measles virus of CAM-70 strain, not less than 1,000-CCID₅₀

ACTION AND MODE OF MECHANISMS OF ACTION

Measles Vaccine stimulates active immunity of human body to promote the development of antibodies against Measles.

PHARMACOLOGY (SUMMARY OF PHARMACODYNAMICS AND PHARMACOKINETICS)

Not applicable.

TOXICOLOGY (Brief)

Incompatibility and Specific Toxicity Tests were conducted on adult mice and guinea pigs. The results showed no sign of abnormality and death.

INDICATIONS :

For the prevention of Measles in all children up to the age of 9 months.

CONTRAINDICATIONS :

- Acute or developing infectious disease.
 - Developing malignant disease (Leukemia, Lymphoma or generalized malignancy)
 - Congenital or acquired immunodeficiency or immunosuppression treatment.
 - Pregnancy.
 - Allergy to eggs.
 - Recent gammaglobulin injection or blood transfusion until 6 weeks to 3 months.
- However, HIV infected persons, both asymptomatic and symptomatic, should be immunized with Measles Vaccine according to the standard schedule.

SIDE EFFECTS / ADVERSE REACTIONS:

A mild fever (up to 38 °C) and rashes lasting up to three days may be observed between the 6th and 12th day after vaccination in up to 10% of vaccinees. Slight digestive tract disorders, rhinopharyngitis may occur. Encephalitis has been reported in approximately one case per million doses administered.

PRECAUTIONS / WARNINGS :

- Shake well before use.
- Vaccine is injected subcutaneously, preferably in the upper arm.
- A sterile needle and syringe must be used for each injection.
- Once the vaccine has been reconstituted, it should be used within 6 hours in the same day when stored between 0 to 8 °C and protected from light.
- The diluent  must be kept cool prior to use.

DRUG INTERACTION : Not reported.

PREGNANCY AND LACTATION

Contraindicated in Pregnancy and Lactation.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION:

After reconstitution with first diluent provided, shake well before use. Inject subcutaneously. One 0.5ml injection is sufficient to confer long-term immunity. Measles vaccine is recommended for children after 9 months of age (270-days).

As Vaccination Schedules vary from country to country, the advised schedule for each country must be in accordance with the National Recommendation.

Measles vaccine can be safely and effectively given simultaneously with DT, Td, TT, BCG, Polio vaccine (OPV and IPV), Hepatitis B, and Yellow Fever vaccine.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE, AND ANTIDOTE(S) :

Not documented.

PACKING / PACK SIZES :

Transparent 5ml glass vials of 10 doses each, packed in a box of 10 vials.

STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS:

Measles Vaccine should be stored in a refrigerator between +2 and +8°C. It is preferable to store the vaccine at temperatures < 20°C or lower. It is a good practice to arrange transportation under refrigerated conditions, particularly in hot climates. The diluent should be stored at room temperature.

SHELF LIFE :

When stored under the prescribed condition of temperatures +2 to +8°C, the shelf life of the vaccine is 3 years from the date of release of manufacture.

NAME AND ADDRESS OF MANUFACTURER :

PT. Bio Farma
Jl. Pahlawan 26 Bandung 40131, Indonesia
Tel : 02-22-0003765
Fax : 02-22-2041009

NAME AND ADDRESS OF DISTRIBUTOR IN MALAYSIA :

Propharm (M) Sdn. Bhd.
640A 4th Mile Road, 
64000 Kuala Lumpur,
Malaysia
Tel : 03-62677380 Fax : 03-62612416