

Rubavax-M™

Measles and Rubella Vaccine
(Live, attenuated) USP

Presentation

Rubavax-M™: Each vial contains lyophilized preparation of live attenuated Measles virus (Long-47 strain) grown in chicken embryo cell cultures and live attenuated Rubella virus (RA27/3 strain) grown in human diploid cell. After reconstitution each 0.5 ml contains live, attenuated measles virus USP ≥ 1000 CCID₅₀ and live, attenuated rubella virus USP ≥ 1000 CCID₅₀.

Description

Rubavax-M is a live, attenuated virus vaccine for vaccination against measles (rubeola) and rubella (German measles). Rubavax-M is a sterile lyophilized vaccine prepared from live, attenuated strains of CAM-70 Measles virus propagated on chicken embryo fibroblast (CEF) cell substrate & live, attenuated strains of Wistar RA 27/3 Rubella virus grown on human diploid cell culture. The two viruses are mixed before being lyophilized. Before reconstitution, the lyophilized vaccine is a light yellow compact crystalline plug/powder. When reconstituted as directed, can vary from clear pale yellow to pinkish yellow solution.

Indication and uses

Rubavax-M is indicated for simultaneous immunization against measles and rubella in person older than 8 months.

Dosage and administration

Adults and Children: A single dose of 0.5 ml of the reconstituted vaccine given by deep subcutaneous injection. Do not give intravenously.

EPI schedule: After completion of 9 months, 1 dose of measles-rubella vaccine should be given. After completion of 15 months, 1 dose of only measles containing vaccine should be given.

Contraindication

- Allergic to any ingredient in the vaccine.
- Suffering from acute diseases, severe chronic diseases, acute exacerbation of chronic diseases and fever.
- Pregnant women.
- Immune deficiency, immune dysfunction or receiving immunosuppressive therapy. Suffering from encephalopathy, uncontrolled epilepsy and other progressive neurological diseases

Precaution:

- This product is used with caution in the following cases: with family and personal history of seizures, suffering from chronic diseases, with history of epilepsy, allergic constitution, breastfeeding women.
- The vaccine must not be contacted with the disinfectant when opening vaccine bottle and injecting vaccines.
- The vaccine should not be used if vaccine bottle has cracks or unclear labels, the vaccine is beyond shelf life, and abnormal appearance (such as turbidity) is observed after reconstitution.
- The vaccine should be used immediately after opening.

- Epinephrine and other drugs should be prepared for emergency use in case of occasional severe allergic reaction. The people receiving vaccination should be observed at the site for at least 30 minutes after injection.
- The people receiving injection of immune globulin should be vaccinated with an interval of at least 3 months so as not to affect the immune effect.
- Other attenuated live vaccine should be vaccinated with an interval of at least 1 month from this vaccine, but this vaccine can be vaccinated simultaneously with attenuated live mumps vaccine.
- This product is an attenuated live vaccine and it is not recommended to be used in the epidemic season.
- Women of childbearing age should avoid pregnancy within at least 3 months after injection of this vaccine.
- Freezing is prohibited.

Use in pregnancy & lactation

Pregnancy category C. Pregnancy should be avoided for 3 months following vaccination. Caution should be exercised when Measles and Rubella vaccine is administered to a nursing woman.

Side-effects

Common side-effects :

- (1) Generally pain and tenderness at the injection site may occur within 24 hours after vaccination, which usually disappear by itself within 2-3 days.
- (2) Generally transient fever reaction may occur within 1-2 weeks after vaccination.
- (3) Rash: generally mild rash may occur within 12 days after vaccination, which generally lasts for no more than 2 days.

Rare side-effects:

Severe fever reaction: physical methods and drugs should be used for symptomatic treatment to prevent febrile seizures.

Very rare side-effects:

- (1) Allergic rash: generally urticaria may occur within 72 hours after vaccination, and if this reaction occurs, anti-allergy treatment should be timely given.
- (2) Anaphylactic shock: generally occurs within 1 hour after vaccination. Injection of epinephrine and other emergency measures should be timely given for treatment.
- (3) Anaphylactoid purpura: medical care should be timely given if anaphylactoid purpura occurs. Cortical steroids can be given for anti-allergy treatment. Improper or not timely treatment is likely to cause anaphylatic purpura nephritis.
- (4) Thrombocytopenia purpura.
- (5) Adults may develop arthritis, pain and swelling of large joints after vaccination.

Overdose

Not applicable.

Storage

Keep out of the reach and sight of children. Store at +2°C to +8°C. Transportation should also be at +2°C to +8°C. Do not freeze. Discard vaccine if frozen. Protect from light.

Commercial pack

Rubavax-M™: Each box contains 1 vial lyophilized preparation of Measles and Rubella Vaccine (Live, attenuated) USP, 1 ampoule containing 0.5 ml WFI and a sterile disposable syringe.

Manufactured by
 **Incepta Vaccine Ltd**
Savar, Dhaka, Bangladesh

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