

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

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MEASLES, MUMPS AND RUBELLA VACCINE (LIVE) I.P.

TRESIVAC®

(Freeze-Dried)

COMPOSITION

TRESIVAC (Measles, Mumps and Rubella Vaccine (Live) I.P.) freeze-dried is prepared from live attenuated strains of Edmonston-Zagreb Measles virus propagated on human diploid cell culture, L-Zagreb Mumps virus propagated on chick embryo fibroblast cells and Wistar RA 27/3 Rubella virus propagated on human diploid cell culture. The reconstituted vaccine contains, in single dose of 0.5 ml not less than 1000 CCID₅₀ of Measles virus
5000 CCID₅₀ of Mumps virus
1000 CCID₅₀ of Rubella virus.
Diluent : Sterile Water for Injections.
The vaccine meets the requirements of I.P. and WHO when tested by the methods outlined in I.P. and WHO, TRS 840 (1994).

INDICATIONS

TRESIVAC is indicated for active immunization in children of 12 months to 10 years of age against Measles, Mumps and Rubella infections simultaneously. For Immunisation of children above 10 years and susceptible nonpregnant adult individuals, we recommend to use MR-VAC (Measles and Rubella Vaccine)/R-VAC (Rubella vaccine) while observing certain precautions as indicated under the heading contraindications.

The IAP Committee of Immunisation recommends two doses of MMR vaccine to every child at 15 to 18 months and 5 years. The second dose of MMR vaccine can be given at any time 4 to 8 weeks after the first dose.

MMR vaccine can also be given to adults at any age in case they have missed the vaccination in childhood and or there is no vaccination record available, by giving 2 doses of MMR with an interval of minimum 4 weeks. However, it is important to note that vaccination in adults can cause higher percentage of adverse reactions as compared to childhood vaccination. Amongst these the commonly encountered side reactions are unilateral or bilateral parotitis and fever. To avoid such reactions, if the physician desires, MR vaccine can be recommended instead of MMR vaccine. MMR 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.

ADMINISTRATION AND DOSAGE

The vaccine should be reconstituted with the entire contents of the 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 toddlers and upper arm in older children. If the vaccine is not used immediately then it should be stored in the dark at 2° - 8° C for no longer than 6 hours.

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.

FOR SUBCUTANEOUS USE ONLY

ADVERSE RECTIONS

The type and rate of severe adverse reactions do not differ significantly from the measles, mumps and rubella vaccine reactions described separately.

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.

The mumps component may result in parotitis and low grade fever. Febrile seizures and orchitis may also occur. However, moderate fever occurs rarely and aseptic meningitis has been reported very rarely.

Vaccine-associated meningitis resolves spontaneously in less than 1 week without any sequelae. The onset of aseptic meningitis is delayed, which may limit the ability to detect these cases by passive surveillance. Vaccine associated aseptic meningitis is observed between 15-35 days post immunization.

The rubella component may commonly result in joint symptoms manifested as arthralgias (25%) and arthritis (10%) among adolescent and adult females that usually last from a few days to 2 weeks. However, such adverse reactions are very rare in children and in men receiving MMR vaccine (0%-3%). Symptoms typically begin 1-3 weeks after vaccination and last 1 day to 2 weeks. These transient reactions seem to occur in non-immunes only, for whom the vaccine is important. Low-grade fever and rash, lymphadenopathy, myalgia and paraesthesiae are commonly reported. Thrombocytopenia is rare and has been reported in less than 1 case per 30 000 doses administered. Anaphylactic reactions are also rare. Clinical experience has exceptionally recorded isolated reactions involving the CNS. These more serious reactions have however, not been directly linked to vaccination.

CONTRAINDICATIONS

1. Pregnancy.
2. Leukaemia, Lymphomatoses and other Malignant diseases.
3. Severe febrile diseases.
4. Therapy with Corticosteroids, radiation, cytostatic drugs and Gammaglobulins 3 months prior to vaccination and one and half to three months post-vaccination.
5. History of febrile convulsions or impairment of CNS.
6. History of known hypersensitivity to egg protein.

7. The vaccine may contain traces of neomycin. Anaphylactic or anaphylactoid reactions to neomycin, history of anaphylactic or anaphylactoid reactions to eggs (Hypersensitivity to eggs), are absolute contraindications.

Measles-Mumps-Rubella (MMR) vaccine and its component vaccines should not be administered to women known to be pregnant because a risk to the fetus from administration of these live virus vaccines cannot be excluded for theoretical reasons. Women should be counselled to avoid becoming pregnant for 28 days after vaccination with measles or mumps vaccines or MMR or MR vaccine or other rubella vaccines.

HIV INFECTION

Tresivac may be used in children with known or suspected HIV infection. The vaccine is contraindicated in persons who are severely immunocompromised as a result of congenital disease, 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.

PRECAUTIONS

Do not administer intravenously. Use carefully in case of hypersensitivity to neomycin.

STORAGE

Store between +2° C and +8° C. Protect from light, 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.

PRESENTATION

TRESIVAC is presented as freeze-dried vaccine

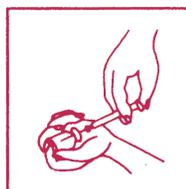
1. 1 dose x 10 vials pack plus diluent (0.5ml Sterile Water for Injections I.P.) and sterile disposable syringe and needle supplied separately.
2. 2 doses x 10 vials pack plus diluent (1 ml Sterile Water for Injections I.P.) and sterile disposable syringe and needle supplied separately.
3. 5 doses x 50 vials pack plus diluent (2.5ml Sterile Water for Injections I.P.).
4. 10 doses x 50 vials pack plus diluent (5ml Sterile Water for Injections I.P.).

MOST IMPORTANT WARNING

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 (0.1-0.5ml of 1:1000 injection) given s/c or i/m. Single dose should not exceed 1 mg (1ml). For infants and children the recommended dose of adrenaline is 0.01mg/kg (0.01ml/kg of 1:1000 injection). Single paediatric dose should not exceed 0.5mg (0.5ml). 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 vaccinees 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.

FREEZE-DRIED PREPARATIONS

Instructions for use



1) Draw the diluent from the ampoule into a syringe, pierce the bung of the vial with the needle and gently inject the diluent into the vial.



2) Detach the syringe, leaving the needle in vial bung. After 15 seconds remove the needle.



3) Rotate the vial gently between your palms till the material dissolves. Avoid shaking the vial as this would cause frothing.



4) Withdraw the reconstituted solution into the syringe, now ready for administration.



Manufactured by:
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Protection from birth onwards

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