เอกสารกำกับยาภาษาอังกฤษ

MEASLES AND RUBELLA VIRUS VACCINE LIVE

DESCRIPTION

The vaccine is prepared from the live, attenuated strains of Edmonston-Zagreb measles virus and Wistar RA 27/3 rubella virus. Both measles and rubella viruses are propagated on human diploid cells (HDC). The vaccine is lyophilized and is provided with diluent. The product has the appearance of a yellowish-white dry cake. The vaccine meets the requirements of WHO when tested by the methods outlined and WHO, TRS 840 (1994).

POTENCY

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

INDICATIONS

For active immunization against measles and rubella in infants, children, adolescents and young adults at risk. Immunization of susceptible non-pregnant adolescent and adult females is indicated if certain precautions are observed (see CONTRAINDICATIONS). The 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.

APPLICATION AND DOSAGE

The vaccine should be reconstituted only with the entired diluent supplied (Sterile water for injection) 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 and 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 (see figure), if present would have been removed on reconstitution.

The diluent supplied is specially designed for use with the vaccine. Only this diluents must be used to reconstitute the vaccine. Do not use diluents from other types of vaccine or for MR vaccine from other manufacturers. Water for injection must NOT be used for this purpose. Using an incorrect diluents 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.

CLOSE ATTENTION SHOULD BE PAID TO THE CONTRAINDICATIONS LISTED

The diluents 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 diluents or reconstituted vaccine.

ADVERSE REACTIONS

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

Clinical experience has exceptionally recorded isolated reactions involving the CNS. These more serious reactions have, however, not been directly linked to vaccination.

DRUG INDICATIONS

Due to the risk of inactivation, the rubella 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.

CONTRAINDICATIONS AND WARNINGS

Individuals receiving corticosteroids, other immuno-suppressive drug or undergoing radio-therapy may not develop an optimal immune response. The vaccine should not be given in febrile states, pregnancy, acute infectious diseases, leukaemia, severe anaemia and other severe diseases of the blood system, severe impairment of the renal function, decompensated heart diseases, following administration of gammaglobulin or blood transfusions or to subjects with potential allergies to vaccine components. The vaccine may contain traces of neomycin. Anaphylactic or anaphylactoid reactions to neomycin, history of anaphylactic or anaphylactoid reactions are absolute contraindications. 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.

MR vaccine should not be administered in pregnant women because of the theoretical but never demonstrated teratogenic risk. Inadvertent receipt of MR vaccine during pregnancy is not an indication for an abortion. Since MR vaccine is recommended in adults, if pregnancy is planned, then an interval of one month should be observed after MR vaccination. No cases of CRS have been reported in any pregnant women who inadvertently received rubella-containing vaccine in early pregnancy.

HIV INFECTION

Measles and Rubella virus vaccine live 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 leukemia 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.

RECOMMENDED STORAGE

IT IS IMPORTANT TO PROTECT BOTH THE LYOPHILIZED AND RECONSTITUTED VACCINE FROM THE LIGHT. The vaccine should be stored in the dark at a temperature between 2° and 8°C. For long term storage a temperature of -20°C is recommended for the lyophilised vaccine. The diluent should not be frozen, but should be kept cool.

SHELF LIFE

30 months from date of last satisfactory potency test, if stored in a dark place at a temperature between 2° and 8° C.

PRESENTATION

1 Dose Vial plus diluents (0.5 ml)

2 Dose Vial plus diluents (1 ml)

10 Dose Vial plus diluents (5 ml)

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 (0.1-0.5 ml of 1:1000 injection) givens 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 (0.01 ml/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 vaccines 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.

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