MODEL INSERT
RUBELLA VACCINE

DESCRIPTION
The rubella vaccine is a live, attenuated viral vaccine. Each dose of this vaccine contains a defined number of active virus particles (>1000 CCID50) (culture infective doses 50%) of viral vaccine strain.....(specify), prepared in …. (specify substrate, diploid cells, MRC5/WI-38) and not more than .....µg of residual antibiotic….. (specify).

<table>
<thead>
<tr>
<th>COMPOSITION</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>0.5 ml</td>
</tr>
<tr>
<td>Rubella</td>
<td>XXX CCID50</td>
</tr>
<tr>
<td>Nature / amount of excipient</td>
<td>XX mg/ml</td>
</tr>
<tr>
<td>Nature / amount of stabilizer</td>
<td>XX mg/ml</td>
</tr>
<tr>
<td>Nature and amount of residual antibiotic</td>
<td>XX µg/ml</td>
</tr>
</tbody>
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Diluent composition

ADMINISTRATION
Rubella vaccine is generally injected subcutaneously. The preferred site of injection is the upper arm. The lyophilizate must be reconstituted by adding the entire content of the supplied container of diluent to the vaccine vial. The vaccine pellet should be completely dissolved in the diluent. Following reconstitution, the vaccine should be inspected visually for any foreign particulate matter prior to administration. If observed, the vaccine must be discarded. A sterile needle and sterile syringe must be used for the reconstitution of the vaccine and for each injection. Because of sensitivity to ultraviolet light, the vaccine must be stored in the dark at +2°C and +8°C and used 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 diluents from other types of vaccine or for measles vaccine from other manufacturers. Using an incorrect diluent may result in damage to the 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.

IMMUNIZATION SCHEDULE
Rubella vaccine is usually administered at the age of 12-15 months, but can also be administered to children as young as nine months of age. In most countries the vaccine is given as MR or MMR, and the age of administration is chosen based on the appropriate age for measles vaccination. Rubella vaccine may also be administered to older children, adolescents, students, child care personnel, health care workers, military personnel, and adult men in contact with women of childbearing age.
Rubella vaccination should be avoided in pregnancy because of the theoretical (but never demonstrated) teratogenic risk. If pregnancy is being planned, then an interval of one (1) month should be observed after rubella immunization. No serious cases have been reported in more than 1000 susceptible pregnant women who inadvertently received a rubella vaccine in early pregnancy. Rubella vaccination during pregnancy is not an indication for abortion.

The Rubella vaccine can be given safely and effectively simultaneously with measles, mumps, DTP, Td, TT, BCG, polio (OPV and IPV), Haemophilus influenzae type b, Hepatitis B, or yellow fever vaccines or vitamin A supplementation.

**SIDE EFFECTS**

Side effects following rubella vaccination are mild, particularly in children. Common side effects include pain, redness and induration at the site of injection. Low-grade fever and rash, lymphadenopathy, myalgia and paraesthesiae are commonly reported. Joint symptoms tend to be rare in children (0% -3%) and in men, but are common among vaccinated adolescents and adult females; they include arthralgias (25%) and arthritis (10%) that usually last from a few days to two (2) weeks. These transient reactions seem to occur in non-immune individuals only, for whom the vaccine is important. Thrombocytopenia is rare and has been reported in less than 1 case per 30,000 doses administered. Anaphylactic reactions are also rare.

**CONTRAINDICATIONS**

A previous allergic reaction to rubella vaccine is a contraindication. Persons with a history of an anaphylactic reaction to... *(specify the antibiotic(s) used as preservative)* should not receive the vaccination. Low-grade fever, mild respiratory infections or diarrhoea, and other minor illnesses should not be considered as contraindications. On theoretical grounds rubella vaccine should be avoided during pregnancy.

**Immune deficiency**

The 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 treatment with high-dose steroids, alkylating agents or anti-metabolites, or in persons who are receiving immunosuppressive therapeutic radiation. However, asymptomatic HIV-positive persons can be immunized. Children with malignant disease or who have had a bone marrow transplant should be immunized against rubella six (6) months after immunosuppressant treatment is stopped. Vaccination should be postponed if the potential vaccine has a serious illness. Persons with active tuberculosis should not be vaccinated until treatment has been established.

**STORAGE**

Freeze-dried rubella 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 rubella vaccine should also be kept frozen at -20°C.

**PRESENTATION**

The vaccine comes in vials of .... dose(s).
The Vaccine Vial Monitors (VVMs) are on the cap of ……(specify vaccine) supplied through ………(specify supplier or manufacturer). The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, then the vial should be discarded.

Revised on December 2005