



**rubella vaccine, live, freeze-dried,
RA 27/3, HDC**
vaccinum rubellae vivum, lyophilisatum

composition

Each single 0.5 ml dose of the reconstituted vaccine contains:
- rubella virus, RA 27/3, HDC not less than 1000 CCID₅₀

Excipients:

Sorbitol, gelatine, L-arginine HCL, maltose, sodium chloride, lactalbumin hydrolysate, L-alanine.

properties

The vaccine is a lyophilised preparation of live, attenuated RA 27/3 rubella virus strain, obtained by propagation in a culture of human diploid cells (HDC).

Immediately prior to use, the freeze-dried vaccine is reconstituted in the sterile water for injection provided. Due to minor variations of its pH, the vaccine solution may vary in colour from light yellow to light pink.

indications

The vaccine produces active immunization against rubella. In order to achieve an optimal immune reaction, the vaccine should be administered at an age when the child loses passive protection from the mother's antibodies. Live, attenuated rubella vaccine is recommended for persons over 12 months of age. Women of childbearing age who are professionally exposed to rubella infection should especially be vaccinated (women employed in medical institutions, preschool and schools).

Through immunization with the combined measles, mumps and rubella (MMR) vaccine according to the vaccine protocol of two doses, the majority of children and adolescents receive two doses of rubella vaccine. Rubella vaccine as an integral component of the MMR vaccine is recommended at 12 to 15 months of age; the second dose of MMR vaccine is routinely administered at 6 to 7 years of age (or according to the immunization schedule prescribed by the Ministry of Health of the Republic of Croatia for each year).

contra-indications

Vaccination is contraindicated in cases of evident immunodeficiency, pregnancy and in cases of recorded data on immunity against rubella. Immunity against rubella is determined: (a) serologically, i.e. the existence of IgG antibodies against rubella in the serum, or (b) by means of a vaccination certificate containing evidence of at least one vaccine dose against rubella prior to or on the first birthday.

A clinical diagnosis of rubella is unreliable and should not be used as a parameter for determining immunity against rubella.

Vaccination is contraindicated in cases of:

- acute infectious diseases;
 - febrile state;
 - within three months following blood transfusion, plasma or immunoglobulin therapy (and longer if large amounts were administered), or within six months following exsanguine transfusion;
 - hypersensitivity to vaccine ingredients.
- Diarrhoea or mild acute upper respiratory disorders and HIV seropositivity are not contraindications for administering the rubella vaccine.

special precautions

- Prior to immunization, it is necessary to take a detailed anamnesis;
- An interval of at least one month should elapse between the administrations of two live vaccines, unless administered simultaneously.

In the event of an eventual anaphylactic reaction, the patient should be treated for shock!

pregnancy and lactation

The vaccine **must not be administered** during pregnancy. Furthermore, pregnancy should be avoided for two months after vaccination due to the presence of the virus in the body.

adverse reactions

Local:

- Pain, redness and swelling at the vaccination site can occur.

General:

- Possible temporary mild symptoms of rubella may occur (rash, swelling of the occipital and cervical lymph nodes, fever, dry throat and headache);
- Acute arthritis and arthralgia.

Frequency of adverse reactions is linked to the age of the vaccine; adverse reactions are more frequent in adults (women of childbearing age).

There is no evidence of a relation between the rubella vaccine (RA 27/3) and the occurrence of various neuropathies and thrombocytopenic purpura.

administration and dosage

The freeze-dried vaccine should be reconstituted immediately prior to use.

For reconstitution of one dose of the vaccine, 0.5 ml water for injection is used.

For reconstitution of five doses of the vaccine, 2.5 ml water for injection is used.

For reconstitution of ten doses of the vaccine, 5 ml water for injection is used.

Using a sterile needle and syringe, withdraw the specified amount of water for injection and inject it into the vial with the freeze-dried vaccine. Shake gently in order to avoid bubble formation. The vaccine dissolves quickly into a uniform suspension. **When the vaccine is packed in multiple doses, it is necessary to use a new sterile needle and syringe for each dose (0.5 ml).**

Prior to vaccination, the vaccine should be heated to body temperature (by holding the filled syringe in the fist). During vaccination, do not allow the vaccine to come into contact with the disinfectant!

The vaccine dose is 0.5 ml. It is injected **subcutaneously** into the forearm, in the deltoid muscle region. From a microbiological point of view, the vaccine should be used immediately. If the vaccine is not used immediately, the user (the person administering the vaccine) is responsible for the time and storage of the opened vaccine. The reconstituted vaccine may be stored for a maximum of 8 hours at a temperature of 2°C to 8°C, unless the vaccine has been opened and reconstituted under controlled and validated aseptic conditions.

interactions with other medicinal products

The rubella vaccine may be administered simultaneously with other live viral vaccines (poliomyelitis, measles, mumps, hepatitis B and yellow fever) and bacterial vaccines (diphtheria, tetanus and whooping cough). Combined viral vaccines such as the measles, mumps and rubella vaccine (MMR) are available on the market. When administering several vaccines simultaneously (Expanded Program for Immunization of the World Health Organization, EPI), mixing other vaccines in the syringe with the rubella vaccine is not recommended.

storage

Store in a refrigerator between 2°C and 8°C, protected from light. Do not freeze.

expiration date

Shelf-life is 24 months. The expiration date is indicated on the packaging.

packaging

- a vial containing 1 dose of the vaccine and an ampoule containing 0.5 ml of water for injection in a box,
- 50 vials in a box, each vial containing 1 dose of the vaccine and 50 ampoules in a box, each ampoule containing 0.5 of water for injection;
- a vial containing 5 doses of the vaccine and an ampoule containing 2.5 ml of water for injection in a box;
- 50 vials in a box, each vial containing 10 doses of the vaccine and 50 ampoules in a box, each ampoule containing 2.5 ml of water for injection.
- a vial containing 10 doses of the vaccine and an ampoule containing 5 ml of water for injection in a box;
- 50 vials in a box, each vial containing 10 doses of the vaccine and 50 ampoules in a box, each ampoule containing 5 ml of water for injection.

The vaccine is subject to medical prescription.

number and date of marketing authorisation in the Republic of Croatia

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