



**measles, rubella and mumps vaccine,
live, lyophilized, Edmonston-Zagreb, HDC;
RA27/3 HDC; and L-Zagreb, CF
vaccinum morbillorum, parotitidis et rubellae vivum,
lyophilisatum**

composition

1 dose of 0.5 ml contains:

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|--|---------------------------------------|
| - measles virus, Edmonston-Zagreb, HDC | not less than 5000 CCID ₅₀ |
| - rubella virus, RA27/3 HDC | not less than 1000 CCID ₅₀ |
| - mumps virus, L-Zagreb, CF | not less than 4000 CCID ₅₀ |

Inactive ingredients:

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

properties

The vaccine is prepared by multiplication of live attenuated viruses: measles (Edmonston-Zagreb strain) and rubella virus (RA27/3 strain) grown in human diploid cells (HDC) and parotitis (L-Zagreb strain) grown in cell cultures of chick fibroblasts (CF) derived from chick embryo of a special closed breed - specified pathogen-free flocks SPF.

Lyophilized vaccine is dissolved with water for injections enclosed with a vaccine package. Due to small differences in pH values, the dissolved vaccine is a clear yellow to clear pink shade.

indications

The vaccine is indicated for active immunization against measles, parotitis and rubella. The vaccine should be used at an age when passive protection through the mother's antibodies is lost in children. The immunization against measles, parotitis and rubella should be obligatory, indicated in children at 12 months of age or older; immunization is also indicated in children up to 18 months of age, or older, if they have not received immunization against these diseases. Additional doses of vaccine against measles, parotitis and rubella should be administered according to the immunization schedule prescribed by the Ministry of Health of the Republic of Croatia for each year.

Persons with histories of contracted measles, parotitis and rubella are also subject to immunization.

contraindications

- pregnancy;
- acute infectious diseases;
- febrile state;
- immune deficiency: primary (congenital) and secondary (caused by a malignant disease or drug use such as antimetabolites, corticosteroids, alkylating agents and radiation);
- within three months following blood or plasma transfusion, or immunoglobulin therapy (or after even longer periods, if greater doses have been used), i.e. within six months after exsanguinotransfusion;
- hypersensitivity to vaccine ingredients.

Although grown in primary culture of chick fibroblasts, there is no evidence of allergic reactions in immunized persons allergic to chicken or chicken feathers. Diarrhoea or light acute diseases of the upper respiratory tract, as well as seropositivity to HIV, are not contraindicated in vaccine usage against measles, parotitis and rubella.

precautions

- a thorough case history should precede immunization;
- in case the vaccinations have not been administered at the same time, a period of at least one month should expire between two immunizations with live virus vaccine;
- tuberculin skin tests (Mantoux test) should be done before, or at least 2 months after administration of measles, parotitis and rubella vaccine, because of a possible occurrence of a transient inhibition of cell immunity;
- children prone to infectious diseases should be immunized, like in asthma, cystic fibrosis, celiac disease, chronic lung disease, congenital heart diseases, Down's syndrome, stable neurological conditions, malnutrition, as well as premature infants regardless of the degree of prematurity.

Antishock therapy should be used in case of possible anaphylactic reaction!

pregnancy and lactation

The vaccine **must not** be used in pregnancy. Conception should be avoided for **two months** after vaccination, because of the presence of the virus in the body. As excretion of the active substances (viruses) in the milk has been described in the literature, the vaccination during lactation should be avoided.

side/adverse effects

Local:

- pain, reddening of skin and burning or stinging at the injection site might appear.

General:

The most frequent reactions to vaccination with live attenuated morbilli vaccine are increased body temperature following approximately one week after vaccination and skin rash. Increased body temperature, parotitis and skin rash appear in rare cases as reactions to the parotitis component. As side effects to the rubella component, arthralgia and arthritis appear to be associated with the age of the immunized persons, i.e. they are reported in up to 2% of girls 6 to 12 and 13 to 16 years of age, in relation to 25% of girls and women 20 to 24 years of age.

There is a scarce amount of data available in relation to the incidence of side effects upon the administration of the second dose of vaccine; a higher risk of side effects is recorded in the age group of 11 to 12 years than in the group of 6 to 7 years of age.

dosing information

The lyophilized vaccine should be diluted immediately prior to use!

0.5 ml water for injection should be taken as a diluent for one dose of vaccine.

1 ml water of injection should be taken as a diluent for two doses of vaccine.

2.5 ml water for injection should be taken as a diluent for five doses of vaccine.

5 ml water for injection should be taken as a diluent for ten doses of vaccine.

A certain amount of diluent should be withdrawn via a sterile needle into the sterile syringe. To obtain a prescribed suspension the diluent should be injected into a vial of lyophilized vaccine and **agitated gently in order to avoid frothing. In multiple-dose vials, a new sterile needle and syringe should be used for each (0.5 ml) dose.**

The vaccine should be heated to body temperature prior to vaccination (by holding in closed fist); the vaccine should not come into contact with disinfectants!

The usual **0.5 ml dose** should be injected **subcutaneously** into the upper arm in the region of the deltoid muscle.

From the microbiological point of view, the reconstituted vaccine should be used as soon as possible. Should the vaccine not be used immediately, the person administering the vaccine should be responsible for its proper storage and labelling. Reconstituted vaccine should be kept at temperatures between 2 °C and 8 °C and used within 8 hours, except in instances where the vaccine has been opened and dissolved in controlled and validated aseptic conditions.

drug interactions

Vaccine against measles, parotitis and rubella may be used simultaneously with other live virus vaccines (vaccine against polio, hepatitis B and yellow fever) and bacterial vaccines (vaccines against diphtheria, tetanus and pertussis). Other commercially available individual vaccines should not be mixed in the same syringe with the measles, parotitis and rubella vaccine (Expanded Program of Immunization of the World Health Organization).

storage

Store the vaccine at 2 to 8 °C protected from light.

shelf-life

The expiry date of the vaccine is indicated on the package.

package

- single-dose vial of vaccine with 0.5 ml ampoule of water for injection in a box
- 50 vials with a single-dose of vaccine in a box and 50 ampoules with 0.5 of water for injection in a box
- a vial with 2 doses of vaccine and 1 ml ampoule with water for injection in a box
- 50 vials with 2 doses of vaccine in a box and 50 ampoules with 1 ml of water for injection in a box
- a vial with 5 doses of vaccine and 2.5 ml ampoule with water for injection in a box
- 50 vials with 5 doses of vaccine in a box and 50 ampoules with 2.5 ml of water for injection in a box
- a vial with 10 doses of vaccine and a 5 ml ampoule with water for injection in a box
- 50 vials with 10 doses of vaccine in a box and 50 ampoules with 5 ml of water for injection in a box

The vaccine should be used in health institutions only.

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