

RUDIVAX

ATTENUATED RUBELLA VACCINE (WISTAR RA 27/3M STRAIN)

COMPOSITION

Each dose of vaccine contains:

- Powder:
 - live attenuated rubella virus (Wistar RA 27/3M strain)
obtained from culture on human diploid cells at least 1000 CCID₅₀*
 - Diluent:
 - water for injections 0.5 ml
- * CCID₅₀ = TCID₅₀ = cell culture infectious doses 50 %.

PHARMACEUTICAL DOSAGE FORM

Injectable suspension obtained by reconstitution of the powder with the diluent.

- 1 dose vial + syringe or ampoule of diluent 0.5 ml
- 10 dose vial + vial of diluent (5 ml)

MARKETING AUTHORIZATION HOLDER

Aventis Pasteur SA
2, avenue Pont Pasteur, F-69007 Lyon

INDICATIONS

This vaccine is indicated for the prevention of rubella in children of both sexes from the age of 12 months.
This vaccine is advised for use in young girls and in seronegative adult women.

CONTRAINDICATIONS

This medicinal product **MUST NOT BE USED** in the event of:

- allergy to one of the constituents of the vaccine,
- allergic reactions following a previous injection of vaccine,
- immune deficiency, except in certain cases for HIV-infected children,
- pregnancy.

This medicinal product is **GENERALLY NOT RECOMMENDED** in association with cytotoxics, unless on medical advice.

SPECIAL WARNINGS

In children, a first injection of rubella vaccine is recommended between 12 and 15 months of age, combined with measles and mumps vaccination. A second injection is recommended between 3 and 6 years of age, also combined with measles and mumps vaccine.

As for any vaccination, in the event of fever or acute disease, it is preferable to postpone vaccination.

After vaccination, tuberculin tests may sometimes give negative results.

PRECAUTIONS FOR USE

Do not inject by the intravascular route: ensure that the needle does not enter a blood vessel.

In the event of association with a mumps and measles vaccine (other attenuated live vaccines), inject the 2 vaccines at the same time at 2 different sites. If the injection is not administered at the same time, wait 3 weeks before administering the second injection.

Avoid placing the vaccine in contact with the antiseptics used to clean the injection site.

Avoid this vaccine in the event of known allergy to neomycin.

If there is any doubt, do not hesitate to consult your doctor or your pharmacist.

Keep out of the reach of children.

DRUG INTERACTIONS AND OTHER INTERACTIONS

Inform your doctor in the event of recent administration of immunoglobulin, plasma or blood transfusion.

You must inform your doctor or your pharmacist of any on-going treatment, *particularly cytotoxic medicinal products*, in order to avoid potential interactions between medicinal products.

PREGNANCY - LACTATION

Women of childbearing age must only be vaccinated against rubella after it has been confirmed that they are not pregnant. Pregnancy must be avoided in the 3 months following the administration of the vaccine.

If you discover that you were pregnant at the time of the vaccination or in the three months which follow, consult your doctor.

Lactation is not a contraindication for rubella vaccination.

DOSAGE AND METHOD OF ADMINISTRATION

For children, refer to the vaccination schedule (See SPECIAL WARNINGS).

For adolescent and adult women, rubella vaccination consists of a single injection.

Administer by the intramuscular or subcutaneous route.

In all cases, comply strictly with your doctor's prescription.

UNWANTED AND DISTURBING EFFECTS

AS FOR ANY ACTIVE PRODUCT, THIS MEDICINAL PRODUCT MAY INDUCE EFFECTS TO A VARYING DEGREE IN CERTAIN SUBJECTS:

These effects mainly consist of swollen glands in the neck or behind the ears from the fifth day following vaccination and joint pains (fingers, knees, etc...).

In rarer cases, a rash similar to that caused by rubella and a painful inflammatory reaction at the injection site possibly accompanied by moderate fever may be observed.

Rare cases of allergic reactions have been reported.

Exceptional cases of thrombopaenic purpura (rashes composed of red spots or purplish-blue marks varying in size, due to a decrease in the platelets in the blood) have been signalled with rubella vaccination.

Report to your doctor or to your pharmacist any unwanted and disturbing effects which might not be mentioned in this leaflet.

STORAGE

Do not exceed the expiry date stated on the external packaging.

SPECIAL PRECAUTIONS FOR STORAGE

Store at between + 2°C and + 8°C (in the refrigerator).