RUDIVAX
Attenuated rubella vaccine

Please read all of this leaflet before using this medicine.
If you have any questions, or if you are in any doubt, ask your doctor or pharmacist.
Keep this leaflet. You may need to read it again.

COMPOSITION

Composition for one vaccination dose:
The unit dose of reconstituted vaccine contains at least 1000 $TCID_{50}$ of live attenuated rubella virus, strain Wistar RA 27/3M
Diluent: water for injections…….. to 0.5 ml

PHARMACEUTICAL FORM

Powder and diluent for injectable suspension as single dose.

PHARMACOTHERAPEUTIC CLASS

VACCINE AGAINST RUBELLA
(: anti-infectives)

Marketing authorisation holder:
Sanofi Pasteur MSD, SNC
8, rue Jonas Salk – 69007 Lyon – France

Manufacturer:
Sanofi Pasteur SA
2, avenue Pont Pasteur – 69007 Lyon – France

WHEN TO USE THIS MEDICINE

This vaccine is indicated for the prevention of rubella in children of both sexes from the age of 12 months.

It is recommended in particular for girls and seronegative adult women.

TAKE SPECIAL CARE:

WHEN NOT TO USE THIS MEDICINE

This medicine MUST NOT BE USED in cases of:
- allergy to one of the ingredients of this vaccine
- allergic reaction to a previous injection of vaccine
- weakened immune system, except in certain cases in children with HIV infection
- pregnancy

This medicine is GENERALLY NOT RECOMMENDED in combination with chemotherapy, except on the advice of your doctor.

SPECIAL WARNINGS

In children, a first vaccination against rubella is recommended between the ages of 12 and 15 months, in combination with vaccination against measles and mumps. A

second injection is recommended between the ages of 2 and 6 years, also given in combination with the vaccine against measles and mumps.
Like all vaccinations, it is preferable to defer vaccination in cases of fever or acute illness.

After vaccination, tuberculosis tests may sometimes be negative.

PRECAUTIONS
Do not inject intravascularly: make sure that the needle does not pierce a blood vessel.

In the event of combination with a vaccine against mumps and measles (other live attenuated vaccines), inject the two vaccines at two different sites. If the injection is not simultaneous, wait three weeks before giving the second injection.

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

Avoid this vaccine in the event of allergy to neomycin.

USING OTHER MEDICINES
Please tell your doctor if you have recently been given immunoglobulin, plasma or a blood transfusion.

TO AVOID POSSIBLE INTERACTIONS BETWEEN MORE THAN ONE MEDICINE, you must ROUTINELY INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER TREATMENT IN PROGRESS, particularly chemotherapy drugs.

PREGNANCY – BREASTFEEDING

Women of childbearing age should only be vaccinated against rubella after it has been verified that they are not pregnant. Pregnancy should be avoided for three months after administration of the vaccine.

If you discover that you are pregnant at the time of vaccination or in the three months following vaccination, speak to your doctor.

Breastfeeding is not a contra-indication for vaccination against rubella.

HOW TO USE THIS MEDICINE

DOSAGE
In children, follow the vaccination schedule (cf. SPECIAL WARNINGS).
In girls and adult women, vaccination against rubella consists of a single injection.

METHOD AND ROUTE OF ADMINISTRATION
Intramuscular or subcutaneous.

SIDE-EFFECTS
LIKE ANY ACTIVE PRODUCT, THIS MEDICINE MAY CAUSE SIDE-EFFECTS IN SOME INDIVIDUALS:

These most often involve glands in the neck or behind the ears, from the 5th day following vaccination, as well as pain in the joints (fingers, knees etc.).

More rarely, a skin rash similar to that caused by rubella may be observed, as well as an inflammatory and painful reaction at the injection site which may be accompanied by moderate fever.

Rare cases of allergic reactions have also been reported.

Exceptional cases of thrombocytopenic purpura (rashes consisting of red dots or purplish spots of variable width, due to a decrease in platelets in the blood) have been reported in vaccination against rubella.

INFORM YOUR DOCTOR OR PHARMACIST OF ANY SIDE-EFFECT NOT MENTIONED IN THIS LEAFLET.

STORAGE

DO NOT USE AFTER THE EXPIRY DATE STATED ON THE OUTER PACKAGING.

SPECIAL PRECAUTIONS FOR STORAGE

This vaccine must be stored at a temperature between +2°C and +8°C (in the refrigerator).

Revised October 2005