ROUVAX

ATTENUATED MEASLES VACCINE (SCHWARZ STRAIN)

COMPOSITION

Each dose of vaccine contains:

• Powder:

– live attenuated measles virus (Schwarz strain) . . . . . at least 1000 $CCID_{50}$*

– human albumin . . . . . q.s. for lyophilisation

• Diluent:

– water for injections . . . . . 0.5 ml

* $CCID_{50}$ = $TCID_{50}$ = cell culture infectious dose 50 %.

This vaccine contains traces of neomycin.

This vaccine is in conformity with W.H.O specifications.

PHARMACEUTICAL DOSAGE FORM

Suspension for injection, obtained by reconstitution of the powder with the diluent.

– Powder: 1 dose or 10 dose vial
– Diluent: 1 dose ampoule or syringe (0.5 ml)
10 dose vial (5 ml)

MARKETING AUTHORIZATION HOLDER

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

INDICATIONS

This medicinal product is a vaccine for the prevention of measles, in children from 9 months of age.

CONTRAINDICATIONS

This medicinal product MUST NOT BE USED in the following cases:

– true allergy to egg protein,
– known allergy to any of the constituents of the vaccine,
– allergic reaction following a previous injection of vaccine,
– congenital or acquired immune deficiency, except in certain cases in children suffering from HIV-infection,
– during pregnancy.

This medicinal product is GENERALLY NOT RECOMMENDED, unless your doctor advises otherwise, in combination with cytotoxics.

If there is any doubt, it is essential to consult your doctor or your pharmacist.

SUBJECTS INFECTED WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)

This vaccine is contraindicated for subjects suffering from immune deficiency. However, asymptomatic or symptomatic HIV-infected subjects should be vaccinated against measles according to the usual schedule.

SPECIAL WARNINGS

– Is in all vaccination, in the event of fever or acute illness it is better to postpone vaccination.
– After vaccination, tuberculin tests can sometimes be negative.

PRECAUTIONS FOR USE

The vaccine having been produced on cultures of chicken embryo cells, there is a possibility of a hypersensitivity reaction in patients exhibiting hypersensitivity to egg proteins (anaphylactic reaction after ingestion of eggs).

This vaccine should be avoided in the event of known allergy to neomycin.

Do not inject by the intravascular route. When giving the injection, make sure that the needle does not penetrate a blood vessel.

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

Keep out of the reach of children.

INTERACTIONS WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION

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

The measles vaccine can be administered at the same time as the DT, Td, TT, BCG, poliomyelitis (OPV and IPV) vaccines and the hepatitis B and yellow fever vaccines in complete

safety without affecting its efficacy.
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 - BREAST FEEDING

This vaccine is contra-indicated during pregnancy. If you discover you are pregnant just after using this vaccine, consult your doctor.

As a general rule, during pregnancy and breast feeding, it is always recommended to ask your doctor's or pharmacist's advice before using a medicinal product.

DOSAGE

Refer to the vaccination schedule.
In general, the first injection is administered at the age of 12 months.
In children in public care structures, this limit is lowered to 9 months.
A second injection is recommended between 3 and 6 years of age.

METHOD AND ROUTE OF ADMINISTRATION

Subcutaneous or intramuscular route.
Once reconstituted, the vaccine must be used immediately (within six hours following the reconstitution) and only if it has been stored between + 2°C and + 8°C and protected from light. The solvent must be kept in a refrigerator until its use.
All reconstituted vaccines have a colour which can vary from pale yellow to clear pinkish yellow.
Use a sterile new syringe and needle for each injection.

SIDE EFFECTS

Like any active product, this medicinal product may in certain persons cause effects which are disturbing to a greater or lesser extent:

- Reactions which are usually moderate and transient may be observed in the two weeks following the injection:
  - fever, rhino-pharyngeal or respiratory symptoms of short duration, and, generally discreet skin reactions.
- Rare cases of swollen lymph glands have been observed.
- Exceptional cases of thrombopaenic purpura have been signalled (rashes composed of red spots or purplish-blue marks varying in size, due to a decrease in the platelets in the blood).

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

The lyophilised vaccine should be stored at a temperature below + 8°C.
The diluent should be stored in a cool place (between + 2°C and + 8°C). When the vaccine is not to be distributed or administered immediately, it is recommended to keep the vaccine powder (and not the diluent) at a temperature of – 20°C.
Protect from light.

Rev. 06/2000