Rancangan Insert Trimovax Merieux

TRIMOVAX MÉRIEUX
LIVE ATTENUATED VIRUS VACCINE AGAINST MEASLES (SCHWARZ STRAIN), MUMPS (URABE AM-9 STRAIN) AND RUBELLA (WISTAR RA 27/3M STRAIN)



COMPOSITION
Each dose of vaccine contains:
• Lyophilisate:
- live attenuated virus:
  - measles (Schwarz strain)……at least 1000 $CCID_{50}$*
  - mumps (Urabe AM-9 strain)……at least 5000 $CCID_{50}$*
  - rubella (Wistar RA 27/3M strain)……at least 1000 $CCID_{50}$*
- human albumin……q.s. for lyophilisation

• Diluent
- water for injections……0.5 mL

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

PHARMACEUTICAL FORM
Solution for injection, obtained by reconstitution of the lyophilisate with the diluent.
- Box of one single dose vial of freeze-dried vaccine with one syringe of diluent.
- Box of ten single dose vials of freeze-dried vaccine. Each vial should be reconstituted with 0.5 mL of of diluent (water for injections).
- Box of ten ten-dose vial of freeze-dried vaccine. Each vial should be reconstituted with 5 mL of diluent (water for injections).

MARKETING AUTHORIZATION HOLDER & MANUFACTURER
SANOFI PASTEUR SA
2, avenue Pont Pasteur, F-69007 LYON, France

INDICATIONS
This medicine is a VACCINE.
Combined prevention of measles, mumps and rubella, from 12 months of age in children of both sexes.
For children in a collective environment (day care center), this limit is reduced to 9 months.
This vaccine is recommended in children. For adult vaccination, RUDIVAX vaccine and IMOVAX MUMPS should be preferred for rubella immunization and for mumps immunization respectively.

CONTRAINDICATIONS
Congenital or acquired immunodepressions (including infections by the human immunodeficiency virus HIV).
An infection by the HIV shoul not be a contraindication to the vaccination against measles, mumps and rubella but in such a case, it is nevertheless rcommended to seek advice from a specialized pediatric team.
True allergy to egg proteins (anaphylactic reaction after eating eggs).
Recent injection of immunoglobulins (See DRUG INTERACTIONS AND OTHER INTERACTIONS).
Pregnancy (See PRECAUTIONS FOR USE), however vaccination during an unknown pregnancy does not justify advising termination of the pregnancy.

PRECAUTION FOR USE
Do not give intravenously. Vaccination should be differed for 6 weeks to 3 month, following blood or plasma transfusions, or administration of human immune serum globulin.
Use carefully in case of hypersensitivity to neomycin and kanamycin.
Due to its rubella component, post-pubertal women should not be given TRIMOVAX MÉRIEUX vaccine in case of pregnancy at the time of the planned injection. They should be advised not to get pregnant during both months following the injection.
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
Due to the risk of inactivation, the rubella vaccine should not be given within the 6 weeks, and if it is possible the 3 months, after an injection of immunoglobulins or blood product containing immunoglobulins (blood, plasma).
For the same reason, immunoglobulins should not be administered within the two weeks after the vaccination.
Tuberculin -positive individuals may transitionally become tuberculin negative after vaccination.
In order to avoid possible interactions between several medicinal products, any other ongoing treatment should be systematically reported to your doctor or your pharmacist.

DOSAGE
In any case, do strictly conform to your doctor's prescription.
As a general guide, the first injection is administered from 12 months of age.
A second injection is recommended between 3 and 6 years of age.

MODE AND ROUTE OF ADMINISTRATION
Subcutaneous or intramuscular route.
TRIMOVAX MÉRIEUX vaccine is in the form of a powder. After reconstitution, it is clear, yellow to purple red.
Any reconstituted vaccine should be used immediately.

SIDE EFFECTS
Skin eruptions may occur, which consist of small red spots or purplish marks of variable size.
The combined vaccination is well tolerated in children.
Minor reactions might be observed from the 5th day after injection: hyperthermia (which may be prevented by using antipyretic drugs), short-lasting rhinopharyngeal or respiratory symptoms, mild exanthem. Hyperthermia convulsions have been rarely observed.
Adenopathies or parotidis have been more rarely observed.
Rare cases of neurological diseases, like meningitis or meningo-encephalitis and unilateral deafness have been reported.
Meningitis occurs during the 30 days following the administration of the vaccine. A mumps virus was sometimes isolated from the cerebro-spinal fluid. In a few rare cases, a characterization method based upon viral amplification and nucleotidic has allowed the identification of the vaccine virus (Urabe AM-9 strain).
The frequency of non bacterial meningitis is greatly less than those caused by wild mumps virus. A complete recovery without any sequella has been usually reported.
The occurrence of orchitis has been very rarely reported.
A few cases of thrombocytopenia have been observed during trivalent vaccination measles, mumps, rubella.
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 between + 2°C and + 8°C protected from light.

PACKAGE:
Box, 1 vial of lyophilized + 1 prefilled syringe of diluent 0.5 mL, Reg. No. DKI0159700744A1

Imported by: PT Aventis Pharma, Jakarta, Indonesia
For PT. BIO FARMA, Bandung.

Harus dengan resep dokter

sanofi pasteur