Registration No. : 2C 49/32

Importer / Manufacturer: Sanofi Pasteur Ltd., Thailand/ Sanofi Pasteur S.A., France

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT : TRIMOVAX MERIEUX

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of vaccine contains:

• Lyophilisate:

– live attenuated virus:

- measles virus (Schwarz strain) cultivated on primary culture of chicken embryo cells . . . . . ….... . . . at least 1000 CCID50*
- mumps virus (Urabe AM-9 strain) cultivated in embryonated hen eggs . . . . at least 5000 CCID50*
- rubella virus (Wistar RA 27/3M strain) cultivated on human diploid cells . . . . . ……... . . . . . at least 1000 CCID50*

* CCID50 = TCID50 = cell culture infectious dose 50%.

3. PHARMACEUTICAL FORM

Solution for injection, obtained by reconstitution of the lyophilisate with the diluent.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicine is a VACCINE.

It is indicated for the combined prevention of measles, mumps and rubella from 9-12 months of age.

For adult vaccination, RUDIVAX vaccine and IMOVAX MUMPS should be preferred for rubella immunisation and for mumps immunisation respectively.

4.2 Posology and method of administration

Dosage:

In any case, do strictly conform to your doctor's prescription.

The first injection is administered from the age of 9-12 months and the second injection is recommended between 4 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.

4.3 Contraindication

Congenital or acquired immunodepressions (including infections by the human immunodeficiency virus HIV).

An infection by the HIV should not be a contraindication to the vaccination against measles, mumps and rubella, but, in such a case, it is nevertheless recommended to seek advice from a specialized paediatric team.

True allergy to egg proteins (anaphylactic reaction after eating eggs).

4.4 Special warnings and precautions for use

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.

4.5 Interaction with other medical products and forms of interaction

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.

4.6 Pregnancy and lactation

Pregnancy (See PRECAUTIONS FOR USE), however vaccination during an unknown pregnancy does not justify advising termination of the pregnancy.

4.7 Effects on the ability to drive and use machines

4.8 Undesirable 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 characterisation 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.

4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

• Diluent:

water for injections . . . . . 0.5 ml

6.2 Incompatibilities

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store between + 2°C and + 8°C protected from light.

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

6.5 Nature and contents of container

– 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 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).

6.6 Special precautions for disposal and other handling

7. MARKETING AUTHORISATION HOLDER

Sanofi Pasteur Ltd., Bangkok, Thailand

8. MARKETING AUTHORISATION NUMBER(S)

2C 49/32

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24 May 1989

10. DATE OF REVISION OF THE TEXT

July 2000

Date of local approval: 30 January 2003

(The above information is based on the currently approved leaflet)