

**Registration No. : 2C.7/53 (B)**

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

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE MEDICAL PRODUCT : TRIMOVAX MERIEUX**

(Live Attenuated Virus Vaccine against Measle (Schwarz Strain), Mumps (Urabe AM-9 strain) and Rubella (Wistar RA 27/3M strain))

### **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 = cell culture infectious dose 50%.

### **3. PHARMACEUTICAL FORM**

Lyophilisate and the diluent for solution for injection

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

This medicine is a VACCINE.

This vaccine is indicated for the combined prevention of measles, mumps and rubella in children from 9-12 months of age.

#### **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).  
HIV-infected individuals who are not severely immunocompromised might be vaccinated after advice from a specialized team.  
True allergy to egg proteins (anaphylactic reaction after eating eggs).  
Recent injection of immunoglobulins (See DRUG INTERACTIONS AND OTHER INTERACTIONS).

### **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 two 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 mumps, measles and 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. In this case, meningitis may occur 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

Diluent: water for injections . 0.5 ml

## **6.2 Incompatibilities**

## **6.3 Shelf life**

3 years

## **6.4 Special precautions for storage**

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

## **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**

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

For multidose presentations when a Vaccine Vial Monitor (VVM) is on the cap  
The Vaccine Vial Monitors (VVM) are on the cap of Trimovax Merieux Vaccine supplied through SANOFI PASTEUR. The colour dot which appears on the cap of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond and acceptable level.



✓ Inner square lighter than outer circle. **If the expiry date has not been passed, USE the vaccine.**



✗ **Discard point:** inner square matches colour of outer circle. **DO NOT USE the vaccine.**



✗ **Beyond the discard point:** inner square darker than outer circle. **DO NOT USE the vaccine.**

The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the circle, then the vaccine can be used. As soon as the colour of the central square is the same colour as the circle or of a darker colour than the circle, then the vial should be discarded.

## 7. **MARKETING AUTHORISATION HOLDER**

Sanofi Pasteur Ltd., Bangkok, Thailand

## 8. **MARKETING AUTHORISATION NUMBER(S)**

2C 7/53 (B)

## 9. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

31 August 2010

## 10. **DATE OF REVISION OF THE TEXT**

July 2000

Date of local approval: 21 February 2012

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