Des réactions minimes peuvent être observées à partir du 5e jour suivant l'injection : hyperthermie (pouvant être prévenue par un antipyrétique), symptômes rhinopharyngés ou respiratoires de courte durée, exanthème discret. La survenue des convulsions hyperthermiques est rarement observée.

Plus rarement peuvent s'observer des adénopathies ou une parotidite.

Des rares cas de maladies neurologiques telles que méningites ou méningo-encéphalites, et surdité unilatérale ont été rapportés.

Les méningites apparaissent dans les 30 jours suivant l'administration du vaccin. Un virus ourlien a parfois été isolé du liquide céphalo-rachidien. Dans quelques rares cas, une méthode de caractérisation basée sur l'amplification virale et le séquençage nucléotidique a permis l'identification du virus vaccinal, souche Urabe AM-9.

La fréquence des méningites non bactériennes est largement inférieure à celle des méningites développées par l'infection due au virus sauvage des oreillons. La guérison complète, sans séquelle, a toujours été habituelle.

Le développement d'orchite a été très rarement rapporté.

Quelques cas de thrombocytopénie ont été signalés lors de la vaccination trivalente rougeole, oreillons, rubéole.

Signaler à votre médecin ou à votre pharmacien tout effet non souhaité et gênant qui ne serait pas mentionné dans cette notice.

CONSERVATION

Ne pas dépasser la date limite d'utilisation figurant sur le conditionnement extérieur.

PRÉCAUTIONS PARTICULIÈRES DE CONSERVATION

A conserver à une température comprise entre + 2°C et + 8°C à l'abri de la lumière.

Rév. 07/2000

R.O.R.

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 virus (Schwarz strain) cultivated on primary culture of chicken embryo cells ..... at least 1000 $CCID_{50}$*
- mumps virus (Urabe AM-9 strain) cultivated in embryonated hen eggs ..... at least 5000 $CCID_{50}$*
- rubella virus (Wistar RA 27/3M strain) cultivated on human diploid cells ..... 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%.

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 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

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

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 immunisation and for mumps immunisation respectively.

CONTRAINDICATIONS

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).

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.

PRECAUTIONS FOR USE

Due to its rubella component, post-pubertal women should not be given R.O.R. 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.

R.O.R. 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 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.

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.

Rev. 07/2000

R.O.R.

VACUNA DE VIRUS VIVOS ATENUADOS CONTRA EL SARAMPIÓN (CEPA SCHWARZ), LAS PAPERAS (CEPA URABE AM-9) Y LA RUBÉOLA (CEPA WISTAR RA 27/3M)

COMPOSICIÓN

Cada dosis de vacuna contiene :

• Liofilizado :

– virus vivos atenuados :

- virus del sarampión (cepa Schwarz) cultivado en cultivo primario de células de embrión de pollo ..... como mínimo 1000 $DICC_{50}$*
- virus de la parotiditis (cepa Urabe AM-9) cultivado en huevos de gallina con embrión ..... como mínimo 5000 $DICC_{50}$*
- virus de la rubéola (cepa Wistar RA 27/3M) cultivado en células diploides humanas ..... como mínimo 1000 $DICC_{50}$*

– albúmina humana ..... c.s. para liofilización

• Solvente :

– agua para preparaciones inyectables ..... 0,5 ml

* $DICC_{50}$ = $DICT_{50}$ = dosis infecciosas en cultivo de células 50 %.

FORMA FARMACÉUTICA

Solución inyectable obtenida por reconstitución del liofilizado con el solvente.

– Estuche de 1 dosis de vacuna liofilizada en frasco + 1 dosis de solvente en jeringa.

– Estuche de 1 dosis de vacuna liofilizada en 10 frascos ; se debe reconstituir cada frasco con 0,5 ml de solvente (agua para preparaciones inyectables).

– Estuche de 10 dosis de vacuna liofilizada en 10 frascos ; se debe reconstituir cada frasco con 5 ml de solvente (agua para preparaciones inyectables).