

Artwork layout of the Product Insert including multilingual text has not yet been provided for publication.

The following English language text was agreed during evaluation for prequalification

ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE**Oral suspension in multidose container****Read all of this leaflet carefully before vaccination**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, if you have a doubt, please ask your doctor or pharmacist for more information.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

In this leaflet:

1. What ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE is and what it is used for
2. What you need to know before you use ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE
3. How to use ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE
4. Possible side effects
5. How to store ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE
6. Further information

1. WHAT ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE IS AND WHAT IS USED FOR

This medicinal product is a vaccine. Vaccines are used to protect against infectious diseases. When this vaccine is injected, the body's natural defenses develop a protection against those diseases.

ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE is indicated in all age groups for primary vaccination and reinforcement of the immunity against poliomyelitis caused by type 3 polioviruses.

The use of this vaccine should be in accordance with official recommendations.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE

Do not use ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE in case of:

- allergy (hypersensitivity)
 - to any component of the vaccine (listed in Section 6 – Further information),
 - to neomycin, streptomycin or polymyxin B (used during manufacturing and which may be present as traces),
- severe reactions after previous administration of an oral poliomyelitis vaccine,
- close contact with patients having immune deficiency,
- primary immune deficiency or immune deficiency subsequent to treatment, leukaemia, lymphoma or advanced malignancy.
Patients with asymptomatic human immunodeficiency virus (HIV) infection should be vaccinated according to the WHO official recommendations.

Warnings and precautions for use

- In the event of vomiting after administration of a dose, a second dose may be given after the symptoms have disappeared.
- In the event of fever or acute disease, it may be recommended to postpone vaccination according to national policy.
- Polioviruses are excreted by vaccinees with a peak in the week following the administration of an oral poliomyelitis vaccine and may contaminate contact persons, including pregnant or breast-feeding women. The safety of the ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE in pregnant or breast-feeding women is not known. Clinical and epidemiological studies have not revealed any congenital malformations or foetotoxic effects related to the oral poliomyelitis vaccine in exposed pregnant women.
- In premature or low birth weight infants, vaccination must be performed at chronological age, without correction related to duration of pregnancy (gestational age) or birth weight.

This vaccine must not be injected.

Other medicines and ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE:

ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE may be given concomitantly during the same vaccination session with injectable inactivated vaccines such as diphtheria, tetanus, pertussis (acellular whole cell) vaccines, the inactivated poliomyelitis vaccine, the *Haemophilus influenzae* type b conjugate vaccine, hepatitis A vaccines and hepatitis B vaccines, pneumococcal conjugate vaccines and with live attenuated vaccines such as measles, rubella, mumps and yellow fever vaccines.

Concomitant administration of the OPV vaccine decreases the immune response to the rotavirus vaccine. However, there is currently no evidence that clinical protection against severe gastroenteritis is modified.

Pregnancy and breast-feeding

Data on the use of this vaccine in pregnant women are limited.

ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE should be given to pregnant women only if clearly needed and following an assessment of the risks and benefits.

Breast-feeding is not a contraindication.

Driving and using machines

The ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE is not expected to have influence on the ability to drive and use machines.

3. HOW TO USE ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE

This vaccine will be administered by a healthcare professional.

Dosage

The vaccine dose is 2 drops (0.1 mL) measured using a multi-dose dropper.

The vaccinating dose can be administered directly in the mouth or on a sugar lump.

If a dropper is used, care must be taken not to contaminate the dropper with the saliva of the vaccinee.

Method of administration

The vaccine must only be administered orally.

Frequency of administration

Primary vaccination or booster doses should be given in accordance with official recommendations.

If you use more ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE than you should:

Few cases of overdose have been reported. No particular actions are to be put in place in case of overdose because the side effects are those described in Section 4.

4. POSSIBLE SIDE EFFECTS

Like all medicine, this vaccine can cause side effects although not everybody gets them.

Since ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE contains one of the three components of the oral trivalent poliomyelitis vaccine, its safety profile is close to the oral trivalent poliomyelitis vaccine safety profile:

- In exceptional cases, Vaccine Associated Paralytic Poliomyelitis (VAPP) due to the reversion of the vaccine virus to neurovirulence may be observed. VAPP may exceptionally present as transverse myelitis. These VAPP cases occur within 4 to 8 weeks following the vaccination. The majority of VAPP cases occur after the first dose. The overall incidence of this type of event varies from one case per 1.4 to 2.8 million vaccinees with the use of an oral trivalent poliomyelitis vaccine. As most cases of VAPP are due to type 2 vaccine poliovirus, the frequency expected with ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE is lower.
- Myalgia (muscle pain) and arthralgia (joint pain).
- General reactions: fever, rigors, asthenia (tiredness).

Reporting of side effects

If you or your child (who was vaccinated) get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE

Keep this medicine out of the sight and reach of children.

Do not use ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE after the expiry date which is stated on the label, the box.

The expiry date refers to the last day of that month.

Store in a freezer (-20°C).

After thawing, the product can be stored for 6 months in a refrigerator (between 2°C and 8°C).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE contains

- The active substance is:
 Poliomyelitis virus type 3*, Léon-12a1b strain, (live, attenuated) at least 5.8 log[†] CCID₅₀[‡]
 For each 0.1-mL dose (2 drops)
 - * Produced in Vero cells
 - † Previously expressed as "at least 10^{5.8} CCID₅₀"
 - ‡ CCID₅₀: 50% Cell Culture Infective Doses (viral infectious units).
- The other ingredients are:
 Human albumin, HEPES buffer solution, magnesium chloride solution (containing polysorbate 80 and phenol red).

The vaccine fulfils the WHO requirements.

What ORAL MONOVALENT TYPE 3 POLIOMYELITIS VACCINE looks like and contents of the pack

This vaccine is an oral suspension in a multidose vial (2-mL vial – 20 doses of 0.1 mL) – Box of 10 vials.

Marketing Authorisation Holder

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This leaflet was last revised on 10/2015.

The following information is intended for healthcare professionals only:

The vial must be shaken gently to avoid any foaming, but sufficiently to obtain a homogenous mixture of the contents.

Obtaining one or several vaccine doses out of one multidose vial essentially depends on the care of handling.

After first and any subsequent opening, the multidose vial should be kept between 2°C and 8°C.

Multi-dose vials from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions in compliance with the WHO Multi-Dose Vial Policy.

The vaccine must be administered exclusively by the oral route.

After use, remaining vaccine, vials and also spoons should be disposed of safely, preferably by heat inactivation or incineration, according to locally agreed procedures.