

لحقاً للـ WHO وقرار اللجنة العلمية المتخصصة للأصول والمقاييس والتقييم لمبادئ
للمستحضرات الطبية ومستندات إلم بلاغوة اللجنة العلمية المتخصصة للأصول والمقاييس
والمبتسرين بجلستها في ٢٠٢٠ / ١١ / ٢٩
د. سلفيا مريده



Bilthoven Biologicals

Shelf life

The shelf life is 36 months.

Special precautions during storage

The vaccine requires a storage temperature between 2 and 8°C. Do not freeze.

Single dose use immediately after opening.

After opening a multidose vial (containing 5 doses) store between 2 and 8°C and use within 28 days.

Packaging

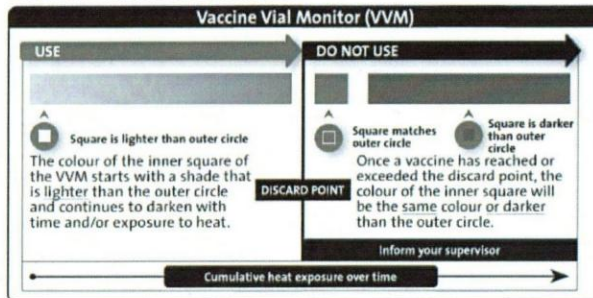
The vaccine is filled in vials (type 1 hydrolytic glass) and sealed with a rubber stopper (free of latex) and an aluminium flip-off cap and contains 0.5 mL vaccine (single dose) or 2.5 mL vaccine (multidose).

Special instructions for use and disposal.

No specific requirements.

Vaccine Vial Monitor (if present on the vial):

The Vaccine Vial Monitor (VVM) is present on the vial in the form of a colour dot. 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 an acceptable level. 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 ring, the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or darker, the vial should be discarded.



MARKETING AUTHORIZATION HOLDER

Bilthoven Biologicals B.V.
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MARKETING LICENSE

Poliomyelitis vaccine is licensed in the Netherlands under number RVG 17642
Poliomyelitis vaccine multidose is licensed in the Netherlands under number RVG 114720

DATA OF FIRST LICENSE OR LICENSE RENEWAL

First license monodose; December 2nd, 1993
License renewal; August 25th, 1994
First license multidose (5-dose); November 12th, 2014

VERSION

WHO package insert, version August 2020

POLIOMYELITIS VACCINE

Package leaflet: Information for the user

NAME

Poliomyelitis vaccine, suspension for injection

COMPOSITION

One dose of 0.5 mL poliomyelitis vaccine contains the following active components:

Inactivated poliomyelitis virus type 1 (Mahoney)*	40 D-antigen units
Inactivated poliomyelitis virus type 2 (MEF 1)*	8 D-antigen units
Inactivated poliomyelitis virus type 3 (Saukett)*	32 D-antigen units

For a list of excipients see pharmaceutical data.

*) Cultivated on Vero-cells.

PHARMACEUTICAL COMPOSITION

Suspension for injection. The product is a suspension of formaldehyde inactivated and purified virus filled in single-dose or multidose (5 doses) vials. The vaccine colour varies from orange-yellow to orange-red.

CLINICAL DATA

Therapeutic indications

Active immunization against poliomyelitis.

Dosage and administration

One dose consists of 0.5 mL for both children and adults. The vaccine is given subcutaneously or intramuscularly. Primary immunization consists of three vaccinations, administered with a minimum interval of 4 weeks. Infants should receive the primary series within the first 6 months after birth. After completion of the first series of vaccinations, a booster dose can be administered after an interval of at least six months. If local authorities recommend a vaccination schedule that starts before the age of 2 months and/or if the interval between doses is less than 8 weeks, a booster dose should be administered, however not before the age of 9 months. This vaccine must be used in accordance with current national recommendations and according to WHO recommendations. Persons fully immunized against poliomyelitis and leaving to areas with a high incidence of poliomyelitis, are advised to re-vaccinate with a single-dose of polio vaccine approx. 1 month before departure, particularly when their last immunization was more than 15 years ago.

Contra-indications

The general contra-indications that apply for every vaccine:

- Previous severe reaction after vaccination with the same vaccine.
- Known hypersensitivity to one or more components of the vaccine
- Do not administer if the vaccinee is suffering from a severe infection, with fever.

Pre-cautions prior to vaccine administration

The vaccine colour may range from orange-yellow to orange-red. Vaccine with a clearly yellow or violet colour cannot be used.

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سلفيا مريده
٢٠٢٠ / ١١ / ٢٩

Do not administer if the vaccinee is suffering from a severe infection, with fever.

Older children and adults can faint after vaccination. This generally occurs shortly after vaccination and can occur simultaneously with nausea and vomiting. If fainting at earlier vaccinations has occurred or symptoms indicating fainting have been observed the person should be vaccinated when sitting or laying.

Under no circumstances administer Poliomyelitis vaccine intravascular

As for any vaccine, adequate treatment provisions need to be present, in case an anaphylactic reaction should occur following vaccination. If required injections of epinephrine or corticosteroids can be given dosed according age and or body weight.

Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with IPV according to standard schedules.

If Poliomyelitis vaccine is administered to individuals with an immune deficiency or under going any type of immunosuppressive therapy the expected immune response can fail to occur.

The potential risk of apnoea and the need for respiratory monitoring for 48 -72 h should be considered when administering the primary immunisation series to very premature infants (born \leq 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

Interactions with other medications and other forms of interaction
Poliomyelitis vaccine can simultaneously be administered with other vaccines on different injection locations.

Pregnancy and lactation
Data on a large number of exposed pregnancies indicate no adverse effects of Poliomyelitis vaccine on pregnancy or on the health of the foetus/new-born child. However Poliomyelitis vaccine should only be used during pregnancy when there is a clear risk of infection.

Poliomyelitis vaccine can be used during lactation.

Effect of driving skills or capability to operate machines
It is not likely that Poliomyelitis vaccine has an effect on driving skills or the capability to operate machines.

Adverse reactions
Based on Post Marketing information (voluntary reporting) it has been established that the following adverse reactions could occur. The reported adverse reactions following vaccination with Poliomyelitis vaccine mostly occurred within the first three days following vaccination and were temporary of nature.

General disorders and reactions:

Local reactions:

Seldom ($>1/10.000$, $<1/1.000$): Swelling, redness and pain on injection site.

Systematic reactions

Seldom ($>1/10.000$, $<1/1.000$): Fever, discomfort.

Neural disorders

Very Seldom ($<1/10.000$): (Poly-) Neuropathy

Respiratory, thoracic and mediastinal disorders

Apnoea in very premature infants (\leq 28 weeks of gestation)

Overdosing

No cases of overdosing have been reported.

PHARMACOLOGICAL ASPECTS

Pharmacodynamic aspects

Therapeutic category: Viral Vaccines, ATC-code: J07BF03

In animals (monkeys or rats) the administration of the vaccine results in the formation of neutralizing antibodies.

Administration of the vaccine in humans results in the formation of antibodies and immunological memory. Administration of a second dose of the vaccine results in a secondary response characterized by a rapid increase of antibody levels that indicates the existence of immunological memory.

In general, the antibody level is indicative for protection. For poliomyelitis a titer (reciprocal dilution in neutralisation assay) of ≥ 8 is protective. A complete vaccination series of Poliomyelitis vaccine, in general results in protective titers against poliomyelitis type 1, 2 and 3.

The percentage seroprotection in the general Dutch population has been studied in 1995 - 1996 (Immunity to Poliomyelitis in the Netherlands, Am.J.Epid., 2001:153,3). During the decade prior to this investigation, the vaccination level for the primary immunization of DTP-IPV (3 doses at 3, 4 and 5 months) in the Dutch national immunization program was 97%. The age of the investigated persons was in the range of 1 to 79 year. The level of seroprotection can be dependent of the moment of collecting blood samples after vaccination, which was not as in most clinical studies 1 month after vaccination. The interval of blood sampling after vaccination varied depending on the age of the person. Furthermore it needs to be mentioned that the data is obtained using plain Poliomyelitis vaccine or a combination vaccine with a Poliomyelitis vaccine component. The percentage of seroprotection is measured in this study is shown in the following table.

	seroprotection	95% confidence interval
Polio type 1	96.6 %	95.9 - 97.2 %
Polio type 2	93.4 %	92.3 - 94.5 %
Polio type 3	89.7 %	88.3 - 91.0 %

Pharmacokinetics

Not applicable for vaccines.

Pre-clinical safety studies

Pre-clinical studies do not show any special risk for humans. These results are obtained of conventional studies in the area of pharmacological safety and toxicology by repeated administration

PHARMACEUTICAL DATA

List of excipients

Formaldehyde (12.5ug) (E240), 2-phenoxyethanol (2.5mg), Medium 199 primarily consisting of amino acids, minerals and vitamins(0.1ml), disodium hydrogenphosphate dehydrate (E339), potassium chloride (E508), sodium chloride, potassium dihydrogen phosphate (E340), polysorbate 80 (E433), calcium chloride (E509), phenol red and water for injection.

Cases of incompatibility

Not applicable.

