



Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains

Please read the instructions carefully and use under the guidance of a physician.

Special Warning

This product is 2.5mL for 5 doses of administration. Do not vaccinate 2.5mL of vaccine on one subject at one time. Please pay attention to the information of presentation on the vial label before use.

【Drug Name】

Common Name: Sabin 株脊髓灰质炎灭活疫苗（Vero 细胞）

English Name: Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains

Chinese Phonetic Alphabet: Sabinzhu Jisuihuizhiyan Miehuoyimiao (Vero Xibao)

【Composition】

The Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains is formulated with Type I, Type II and Type III Sabin strains which are inoculated respectively on the Vero cell for culturing, virus harvesting, concentration, purification and formaldehyde-inactivation, then mixing together to form the trivalent liquid vaccine. This vaccine complies with WHO's recommendations.

Each dose (0.5mL) contains:

Active Composition: Poliovirus (inactivated)

Type I (Sabin): 15DU

Type II (Sabin): 45DU

Type III (Sabin): 45DU

Excipients: 2-phenoxyethanol, M199 medium (containing amino acids, mineral salts, vitamins, glucose, etc.), sodium hydroxide used for pH adjustment.

【Appearance】

This product is a clear, transparent, object-free and colorless liquid.

【Therapeutic Indication】

This product is indicated for the prevention of poliomyelitis in infants and toddlers aged 2 months old and above.

【Pharmacodynamic Properties】

The antibodies against poliovirus can be produced after vaccination, to prevent poliomyelitis caused by Type I, Type II and Type III poliovirus.

【Presentation】

Each vial contains 2.5mL (5-dose presentation). 0.5mL for each human dose, and each dose contains 15DU D-antigen of Type I poliovirus, 45DU D-antigen of Type II poliovirus and 45DU D-antigen of Type III poliovirus.

【Immunization Regimen and Dosage】

This vaccine will be administered by a healthcare professional, preferably into a muscle



Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains

Please read the instructions carefully and use under the guidance of a physician.

(intramuscular route). The injection into a muscle will be preferably performed in the middle of the outer thigh in infants and in the upper part of the arm in toddlers and children.

For primary vaccination (first series of vaccinations), the first one dose should be injected at the age of 2 months, then two successive doses at an interval of 4-6 weeks. One dose should be injected as a booster at the age of 18 months. 0.5mL per injection.

This vaccine should be used immediately once open.

The immune persistency study of this vaccine has not been conducted.

【Adverse Reactions】

According to the adverse reactions (ARs) of this vaccine reported in domestic clinical trial, the incidence for ARs (CIOMS recommendation) can be presented as: Very common ($\geq 10\%$), common (1-10%, including 1%), uncommon (0.1-1%, including 0.1%), rare (0.01-0.1%, including 0.01%) and very rare ($< 0.01\%$), and detailed ARs are described as follows.

Very Common:

- Pyrexia (moderate, transiently).

Common:

- ARs at the Injection Site: Tenderness, redness.
- Systemic ARs: Agitation, vomiting, somnolence, eating disorder, diarrhea.

Uncommon:

- ARs at the Injection Site: Induration.
- Systemic ARs: Rash.

Very Rare (Refer to the marketed similar vaccines):

- ARs at the Injection Site: Lymph nodes enlarged.
- Allergic Reactions Caused by Any Component of Vaccine: Urticaria, angioedema, anaphylactic shock.
- May occur moderate, transient arthralgia and myalgia.
- May occur convulsions (with or without pyrexia).
- May occur headache, moderate and transient paresthesia (mainly in the lower limbs) within two weeks after vaccination.
- May occur excitation within the first few hours or days after vaccination, but will soon disappear spontaneously.
- Widespread rash.

【Special Warnings and Precautions for Use】

(1) This product is 2.5mL for 5 doses of administration. Do not vaccinate 2.5mL of vaccine on one subject at one time. Please pay attention to the information of presentation on the vial label before use. After the first use, the product should be stored between $+2^{\circ}\text{C}$ and $+8^{\circ}\text{C}$ and finished within 28 days. Sterilize the surface of the rubber stopper before use and avoid cross-contamination strictly. The error of vaccination volume caused by repeat extractions should be minimized. Where a full 0.5mL dose cannot be extracted, the remaining vaccine should be discarded. The remaining vaccine from multiple vials must not be mixed for use.

(2) Intravascular injection is strictly prohibited.



Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains
Please read the instructions carefully and use under the guidance of a physician.

- (3) Drugs and equipment such as epinephrine should be available for emergency treatment in the event of an occasional severe allergic reaction. The vaccinee should be observed for at least 30 minutes after vaccination.
- (4) This vaccine should be used with caution in the following situations:
- ① People who have blood disorders such as decrease in platelets (thrombocytopenia) or clotting disorders because of the risk of bleeding which may occur during intramuscular administration of this vaccine.
 - ② People who are taking a treatment that suppresses the immune defenses or presenting with immune deficiency. The immune response to the vaccine may be reduced. In such cases, it is recommended to postpone vaccination until the end of the treatment or to make sure the subject is well protected. For patients with chronic immune deficiency, this vaccine may also be recommended even though the underlying disease may cause a limited immune response.
 - ③ Patients with uncontrolled epilepsy and other progressive neurological disorders.
- (5) As with any vaccine, a protective immune response may not be elicited in all recipients.
- (6) Do not use disinfectant to contact the vaccine when vial opening and injection.
- (7) This vaccine should be used immediately after open.
- (8) Do not use after the expiration date stated on the box and on the label.
- (9) Do not use if the product has a cloudy appearance or the vial has cracks.
- (10) Keep out of reach of children.

【Contraindications】

This vaccine is strictly prohibited in the following cases:

Individuals who are allergic to any component (active, excipients) of this product, or those who have allergic reactions with this vaccine before.

Individuals who have serious chronic disease or history of hypersensitivity.

Vaccination should be postponed if individuals have fever or during the acute phase of disease.

【Drug Interaction】

If any drugs, including over-the-counter drugs, are being taken or recently taken, please inform the physician in time.

【Overdose】

No overdose data have been obtained from clinical trials or literature reports yet.

【Special Precautions for Storage】

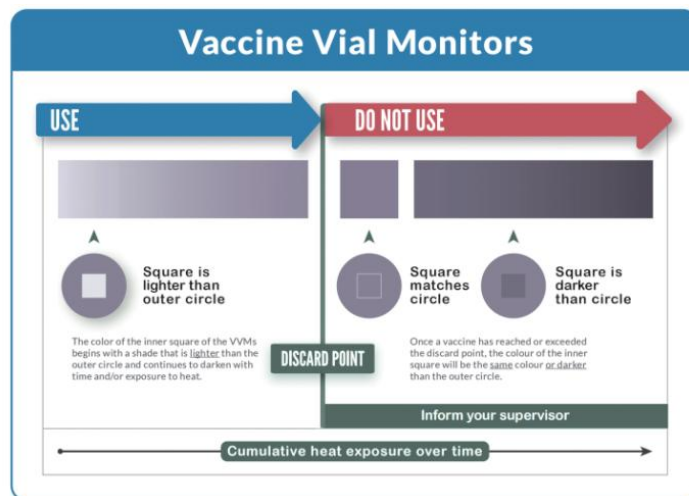
Store and transport in a refrigerated (2°C-8°C) condition, protect from light. Do not freeze.

After first opening, the vaccine can be used for up to 28 days provided it is stored between +2°C and +8°C.



Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains

Please read the instructions carefully and use under the guidance of a physician.



The Vaccine Vial Monitors (VVM) are on the product supplied through Beijing Institute of Biological Products Co., Ltd. The colour dot which appears on the label 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 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, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, then the vial should be discarded. As indicated in the VVM graphic above.

【Packaging Configuration】

Film-coated middle borosilicate glass vial, film-coated brominated butyl rubber stopper. 1 vial/box; 3 vials/box; 10 vials/box.

【Shelf-life】

24 months.

【Executed Standard】

YBS00172017. Pharmacopoeia of the People's Republic of China (2020).

【Authorization Number】

GYZZ S20237012

【Marketing Authorization Holder】

Name: Beijing Institute of Biological Products Co., Ltd.

Address: Room 205, Second Floor, Building 4, No.9 Bo'xing 2nd Road, Economic-Technological Development Area, Beijing, P.R. China.

【Manufacturer】



Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains
Please read the instructions carefully and use under the guidance of a physician.

Name: Beijing Institute of Biological Products Co., Ltd.

Address: No. 6&9 Bo'xing 2nd Road, Economic-Technological Development Area, Beijing, P.R.
China

Post Code: 100176

Telephone: 0086 10 87220568

Fax: 0086 10 87220568

Website: <https://www.bjbpi.com>