Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains

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

【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: 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 2 months and older infants and toddlers.

【Pharmacodynamic Properties】

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

【Immunization Regimen and Dosage】

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

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 trail, the incidence for ARs (CIOMS recommendation) can be presented as: Very common (≥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:

- Fever (moderate, Transiently)

Common:

- ARs at the Injection Site: Pain, 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 fever).
- 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) Intravascular injection is strictly prohibited.

(2) 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.

(3) This vaccine should be used with caution if:

① 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 are taking a treatment that suppresses your immune defence or if you present 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. If you have chronic immune deficiency, this vaccine may also be recommended even though the underlying disease may cause a limited immune response.

③ you have uncontrolled epilepsy and other progressive neurological disorders.

(4) Like all vaccines, this product may not have 100% preventive effect for vaccinee.

(5) Do not use disinfectant to contact the vaccine when vial opening and injection.

(6) This vaccine should be used immediately after open.
(7) Do not use after the expiration date stated on the box and on the label.
(8) Do not use if the product has a cloudy appearance or the vial has cracks.
(9) Keep away from reach of children.

【Contraindications】

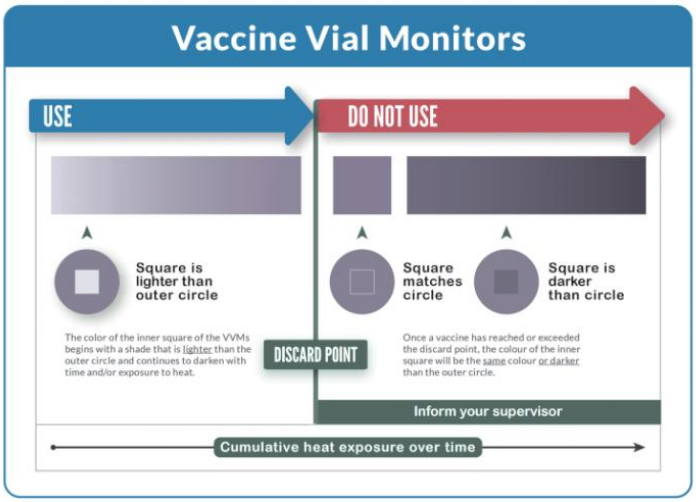
This vaccine is strictly prohibited in the following cases:
Individuals who are allergic to any component (active, excipients) of this product, or those who have allergic reactions with this vaccine before.
Individuals who have serious chronic disease or history of hypersensitivity.
Vaccination should 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.

【Storage】

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



The Vaccine Vial Monitors (VVM) are on the label of 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.

【Shelf-life】 24 months.

【Packaging Configuration】
Film-coated middle borosilicate glass vial, film-coated brominated butyl rubber stopper, 1 vial/box, 3 vials/box and 10 vials/box.

【Executed Standard】
YBS00172017. Pharmacopoeia of the People's Republic of China (2020).

【Authorization Number】
GYZZ S20170006

【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】
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