

Summary of Product Characteristics of Varicella Vaccine, Live I.P. Brand Name: **BIO POXTM**

Manufactured By:

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Summary of Product Characteristics

(As per Annexure C of Module 1 of Guidance for industry by CDSCO)

1. Name of the Medicinal Product :

Generic Name : VARICELLA VACCINE, LIVE I.P.

Brand name : BIO POX™

2. Qualitative and Quantitative Composition :

Each single dose (0.5 ml) of reconstituted Bio Pox™ vaccine contains:

- ≥ 2000 plaque forming units (PFU) of live attenuated Varicella virus (OKA strain) propagated in MRC-5 human diploid cell culture.
- Excipients : KH_2PO_4 - 0.25 mg, K_2HPO_4 - 0.6 mg, L-monosodium glutamate - 0.4 mg, EDTA - 1 mg, Sucrose - 37.5 mg, Human Normal Albumin - 5 mg, Polygeline (Haemaccel®) - 5 mg.

Vaccine Diluent (Sterile water for injection I.P.)

3. Pharmaceutical Form :-

Reconstitute the lyophilizate with the entire content of the diluent provided with the vaccine

4. Clinical Particulars :-

4.1 Therapeutic Indications:-

Bio Pox™ is indicated for active immunization against Varicella virus (Chicken Pox) of healthy subjects with no history of Varicella infection and susceptible healthy close contacts. Bio Pox™ meets the specification of Indian Pharmacopoeia. The manufacturing facilities meet the requirement of cGMP guidelines of revised schedule 'M' of Drugs & Cosmetics Act, Government of India.

4.2 Physiology and method of administration :-

- Reconstitute Bio Pox™ with the entire content of the vaccine diluent (sterile water for injection I.P.) provided with the vaccine. Shake gently for full reconstitution. Each dose (0.5ml) shall be injected immediately after reconstitution by subcutaneous route. Alcohol or other disinfecting agent must be allowed to evaporate from the site of injection before immunization as they may inactivate the vaccine.
- Bio Pox™ is recommended for active immunization of healthy subjects of 1 to 12 years of age.

- IAP (Indian Academy of Pediatrics), recommends 1st dose at 15 months or older, 2nd dose at 4-6 years (can be given 3 months after 1st dose). Catch-up vaccination in children, below 13 years - 2 doses 3 months apart, 13 years or more - 2 doses at 4-8 weeks apart.
- As per WHO position paper on varicella vaccine, two doses induce higher effectiveness and should therefore be recommended in countries where the programmatic goal is, in addition to decreasing mortality and severe morbidity, to further reduce the number of cases and outbreaks.

4.3 Contra-indications :-

- Vaccination is contra-indicated during pregnancy and pregnancy should be delayed for 4 weeks after vaccination. Termination of pregnancy is not indicated if vaccination was carried out inadvertently during pregnancy.
- Ongoing acute or chronic illness like fever, severe infection, persistent diarrhoea, vomiting etc.
- Immuno deficient status/immuno suppressive therapy
- There is no data regarding use in nursing women.
- Hypersensitivity to any component of the vaccine.

4.4 Special warnings and precaution for use :-

- The vaccines should remain under observation for not less than 30 minutes for possibility of occurrence of rapid allergic reactions.
- As with other vaccines, in rare cases anaphylactic shock may occur in susceptible individual. The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be life saving. It should be used at the first suspicion of anaphylaxis. Hydrocortisone & antihistaminic should also be available in addition to supportive measures such as oxygen inhalation.
- As for other Varicella vaccines, cases of Varicella disease have been shown to occur in persons who have previously received Varicella vaccine. These cases are usually mild, with a fewer number of lesions and less fever and cough.
- In case vaccines have not been stored in proper cold chain and or crack/breakage in glass vial, the integrity of pellet/powder of the vaccine could change. In event of the above observed, discard the vaccine.

4.5 Interaction with other medicinal products and other forms of interaction :

- Varicella vaccine can be administered at the same time with other inactivated vaccines or live M/MR/MMR II vaccines; however they shall be administered at different sites.
- There should be one month interval between the inoculation of other live attenuated vaccines.
- Salicylate shall be avoided for 6 weeks after Varicella vaccination as Reye's syndrome have been reported following use of salicylate during natural Varicella infection.
- In subjects who have received immunoglobulins or a blood transfusion, immunization should be delayed for at least 3 months because of the likelihood of vaccine failure due to passively acquired Varicella antibodies.

4.6 Pregnancy & Lactation :

- Vaccination is contra-indicated during pregnancy and pregnancy should be delayed for 4 weeks after vaccination. Termination of pregnancy is not indicated if vaccination was carried out inadvertently during pregnancy.
- There is no data regarding use in nursing women.

4.7 Effects on ability to drive and use machines :

The BIO POX™ vaccine has no effects after vaccination on ability to drive and use machines. No separate studies on was done.

4.8 Undesirable effects :

- Reaction to vaccination generally consists of localized injection site reaction (pain, swelling, redness) and systemic reaction (fever, skin rash, headache, fatigue, vomiting, cough) which are generally relieved spontaneously after one or two days.
- Interspersed rash or blebs may appear to few recipients probably within two weeks after vaccination. No special treatment is necessary. Symptomatic treatment may be helpful in case of need.
- As with any vaccine, there is a possibility that large scale use of vaccine could reveal adverse reactions not observed in clinical trial.

4.9 Over dose :-

Not Applicable.

5. Pharmacological Properties :-

5.1 Pharmacodynamics Properties :

Not applicable for Vaccine as immunizing doses are too less for Pharmacodynamics studies.

5.2 Pharmacokinetic Properties:

Evaluation of Pharmacokinetic properties is not required for vaccine.

5.3 Preclinical Safety Data :

In the preclinical safety Data the BIO POXTM vaccine is found safe.

6. Pharmaceutical Particulars :-

6.1 List of excipients :

Excipients of single dose (0.5 ml) vaccine contains KH_2PO_4 - 0.25 mg, K_2HPO_4 - 0.6 mg, L – monosodium Glutamate - 0.4 mg, EDTA - 1 mg, Sucrose - 37.5 mg, Human Normal Albumin - 5 mg, Polygeline (Haemaccel) - 5 mg.

6.2 Incompatibilities :-

No compatibility studies of BIO POXTM vaccine with other vaccine was done.

In the absence of compatibility studies the medicinal product must not be mixed with other medicinal product.

6.3 Shelf life :-

Store between +2° to +8°C and protect from light. The shelf life of the vaccine is 2 years, if stored at recommended storage conditions.

6.4 Special precaution for storage:-

Store between +2° to +8°C and protect from light. The vaccine is not affected by freezing, stability is even better at lower temperatures.

6.5 Nature & contents of container :-

Materials used for the containerization of Varicella Vaccine Live, I.P. are as follows:

- Glass Vials :-

USP Type-I clear tubular 2 ml glass vials.

- Rubber closures :-

13 mm Grey Butyl Slotted Rubber Stopper (Sterile ready for use).

- Aluminium Seals :-

13 mm flip off PK-1 aluminium seals.

Materials used for the containerization of Vaccine Diluent (Sterile Water for Injection I.P.) are as follows:

- Glass Vials :-
USP Type-I clear tubular 2 ml glass vials.
- Rubber closures :-
13 mm Grey Butyl Rubber Stopper (Sterile ready for use).
- Aluminium Seals :-
13 mm flip off WE-1 aluminium seals.

6.6 Special precautions for disposal:-

No special requirements

7. Marketing authorization Holder:-

BIO-MED (P) LTD.
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Website : www.biomed.co.in

8. Marketing authorization number:-

Form 46 permission No. MF-183/2017 dated 31/07/2017.

9. Date of first authorization/Renewal of the authorization:-

- a) Additional item license vide Letter No. Drug/837/5424 dated 27/10/2017.
- b) Renewal of authorization on Form 26-H dated 21/05/2014.

10. Date of Revision of the text :-

January, 2024.