BiO-MeD PRIVATE LIMITED

PREVENT DISEASES BY VACCINATION

VARICELLA VACCINE, LIVE I.P.
BIO POX™

DESCRIPTION & INDICATION

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 specifications of Indian Pharmacopoeia. The manufacturing facilities meets the requirement of cGMP guidelines of revised schedule `M' of Drugs & Cosmetics Act, Government of India.

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.

SPECIAL PRECAUTIONS 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 mild 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.

DOSAGE AND 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[1] 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[2] 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.

ADDITIONAL STABILITY DATA OF RECONSTITUTED VACCINE

After reconstitution, it is recommended that the vaccine be injected immediately. However the reconstituted vaccine have been found to be stable for 90 minutes when kept at +20°C to +25°C.

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 e.t.c.
- Immuno deficient status/immuno suppressive therapy.
- There is no data regarding use in nursing women.
- Hypersensitivity to any component of the vaccine.

INTERACTIONS

- 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.

POSSIBLE SIDE 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 the vaccine could reveal adverse reactions not observed in clinical trial.

STORAGE AND 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. The lyophilized vaccine is not affected by freezing, stability is better at lower temperatures.

PRESENTATION

Single dose freeze dried vaccine, vaccine diluent (sterile water for injection I.P.) and disposable syringe as combipack.

CLINICAL TRIALS

Bio Pox™ was found to be safe and immunogenic in children against VZV infection[3, 4].

REFERENCES

1. Indian Academy of Pediatrics (IAP) Recommended Immunization Schedule for Children Aged 0 through 18 years – India, 2016 and updates on Immunization.
2. Varicella and herpes zoster vaccines : WHO position paper weekly epidemiological record, No. 25, 2014, 89, 265-288.
3. Phase-I, open, unicentric clinical trial for evaluation of safety of varicella vaccine, Live (I.P.) – Sharma et. al. (2014) Biotechnology International 7 (1) : 26-34.
4. Safety and immunogenicity of Bio-Pox™ , a live varicella vaccine (OKA Strain) in Indian Children: A comparative multicentric, randomized phase II/III clinical trial – Dubey et. al. Human vaccines & Immuno therapeutics 2017, Vol 13, No. 9, 2032-2037.

Manufactured & Marketed by :

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