NEXIPOX®

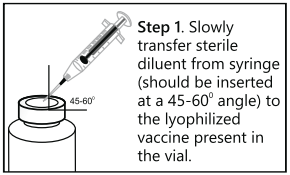
Drug Name
Generic name: Varicella vaccine, Live I.P.

Specification
After reconstitution, each 0.5ml vial/dose of varicella vaccine contains OKA strain ≥ 2000 PFU.

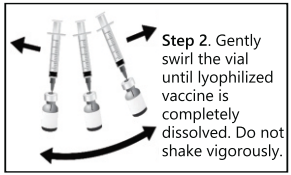
Characters and Constituents
A lyophilized preparation (with appropriate stabilizer) of the live attenuated varicella-zoster virus (OKA strain) obtained by propagation of the virus in human diploid cell culture. The viral suspension is lyophilized to make the vaccine after addition of a suitable stabilizer. This product is a white crisp cake. After reconstitution, it should turn to clear solution without foreign matters.

Function & Use
After vaccination, the body's immune-activity against varicella can be generated for preventing the person from acquiring varicella infection.

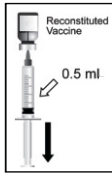
Instructions for reconstitution of the vaccine with the sterile diluent presented in a pre-filled syringe



Step 1. Slowly transfer sterile diluent from syringe (should be inserted at a 45-60^0 angle) to the lyophilized vaccine present in the vial.



Step 2. Gently swirl the vial until lyophilized vaccine is completely dissolved. Do not shake vigorously.



Step 3. After reconstitution, withdraw 0.5 ml from the vial containing the reconstituted vaccine and administer subcutaneously.

Posology and Method of Administration:
1. Reconstitute the vaccine with the Sterile diluent in the syringe and shake the container till the content is reconstituted completely before use.
2. Inject the reconstituted vaccine, subcutaneously at the deltoid insertion area of the lateral aspect of the upper arm.
3. Alcohol and other disinfectant can inactivate the attenuated virus in the vaccine, therefore, the vaccine should be injected immediately after the disinfectant is evaporated completely from the skin.
   Contact with the disinfectant must be avoided.
4. NEXIPOX® should not be administered intra- dermally (ID) or intra-venously (IV). It is recommended to use the vaccine as soon as it is reconstituted.
   DISCARD RECONSTITUTED VACCINE IF NOT USED WITHIN 30 MINUTES.

Indication:
The vaccine is indicated for the active immunization of healthy, varicella susceptible subjects from the age of 12 months.

Dosage:
Children: 2 doses of varicella vaccine should be given from 12 months to 12 years of age, at least 3 months apart in healthy subjects.
Adolescents & Adults: 2 doses of varicella vaccine should be given for primary immunization in healthy subjects 4 to 8 weeks apart.

Undesirable effects/side effects:
Very low overall reactogenicity in all the age groups studied. Reactions at the site of injection are usually mild and temporary.

Contraindications:
1. Subjects with known hypersensitivity to any constituent of this product including neomycin.
2. Women during pregnancy.
3. Subject suffering from serious diseases (acute or chronic infection), fever and any advanced immune disease.
4. Subjects treated with steroidal drug.
5. Subjects with a total lymphocyte count of less than 1200 per mm^3 or presenting other signs of cellular immunodeficiency.
6. Subjects with known history of congenital immune disease or having closely touched with the family member who has a history of this disease.

Warnings & Precaution:
1. It is advisable to have a solution of epinephrine available in the case of anaphylactic reaction.
2. Generally speaking, it is advisable to keep the subject under medical supervision for 30 minutes following vaccination of this product.
3. Transmission of vaccinal virus only occurs in extremely rare cases. Contact should be avoided with patients who may develop severe varicella, such as patient suffering from leukemia or who are undergoing immune-suppressant therapy, especially when the vaccine develops a cutaneous reaction 2 to 3 weeks after vaccination. All contact with pregnant women who may contract varicella should be avoided, especially in the first 3 months of pregnancy.
4. Administered subcutaneously, not intra-demally and never, under any circumstances, intravenously

a. Transfer the sterile diluent from the syringe into the vial containing lyophillized vaccine, shake well to ensure complete dissolution to use.
b. Inject 0.5 ml reconstituted solution subcutaneously at the deltoid area of the upper arm.

5. Contact of any disinfectant with the vaccine of this product during opening and injecting of the vial should be avoided.
6. Do not administer injection in condition of incomplete dissolution of this product, cracked glass vial or syringe and unclear label of glass vial or syringe.
7. **It is recommended to use the vaccine as soon as it is reconstituted with Sterile diluent.**
8. Avoid administration of other vaccines within 1 month following vaccination of this product.
9. Patients with leucocythemia, tumor or immunodeficiency should use the vaccine restrainedly under doctor's guidance.
10. Attenuated live vaccine is not recommended to be used during epidemic seasons.

Interaction with Other Medicine
Product must not be used in case of individuals who have been transfused with whole blood, plasma or immunoglobulins within 5 months before vaccination or within 3 weeks after vaccination as efficacy of vaccine is likely to be reduced. Avoid the use of Salicylate within 6 weeks following vaccination of this product. There should be a one month interval between inoculation of other live attenuated vaccines.

Pregnancy and Lactation
Women of child bearing age can be vaccinated only if appropriate contraceptive measure have been taken for at least 3 months following vaccination. It is not known whether the vaccine is excreted in human milk. Caution should be paid to women in lactation period.

Effects on Ability to Drive & Use Machines
It is not known whether the vaccine may affect the ability to drive and use machines, caution should be paid.

Antidote for Overdosing
Not known

Shelf Life
36 months

Shelf Life After Dilution or Reconstitution
It is recommended to use the vaccine as soon as it is reconstituted with sterile diluent.

Shelf Life After Opening the Container
It is recommended to use the vaccine as soon as possible when it is opened.

Storage
Vaccine should be stored in refrigerator and transported with cold chain between $+2^0C$ to $+8^0C$.
DO NOT FREEZE

Nature and Specification of the container
This pack contains 1 dose vial with freeze-dried vaccine and 0.5ml sterile diluent in pre-filled syringe.
1 Single Dose 0.5ml reconstituted vaccine

Instructions for use
The vaccine must be administered by a professional health care personnel or doctor.
The vaccine should not be inoculated with the same syringe for other vaccines.
The vaccine must under no circumstances to be administered intravenously or intramuscularly.
The vaccine is to be administered by subcutaneous injection only.

You can help by reporting any side effects, you may get after vaccination to Novo Medi Sciences Pvt. Ltd. who is the importer of NEXIPOX® on 24X7 Toll-Free Number: 1800 309 0896 or by E-mail at drugsafety@novomedi.com.
For more information, read this Package Insert carefully.

Manufactured for:
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