NEXIPOX

Drug Name
Generic name: Varicella Vaccine (live) attenuated 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. This product is a milky white crisp in the glass vial. The reconstituted vaccine after dissolution with sterile diluent is a clear solution.

Composition
A Lyophilized vial containing

Varicella Zoster virus, Live Attenuated (OKA Strain)	≥ 2000 PFU
Mannitol	5mg
Dextran	12.5mg
Sucrose	25mg
Trehalose	10mg
Human Albumin	5mg

1 vial with 0.5mL sterile water for injection I.P.

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

Posology and Method Administration:
1. Reconstitute the vaccine with the stated amount of sterile water for injection and shake well to ensure complete dissolution of the milky white crisp cake before use.
2. Inject 0.5ml of 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 can 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-vascularly (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 against varicella of healthy, varicella susceptible subjects from 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 subject, 4 to 8 weeks apart.

Undesirable effects/side effects:

Very low overall reactogenicity in all the age groups is studied. Reactions at the site of injection are usually mild and temporary. In a clinical trial involving 600 infants and children, it was observed that papulovesicular eruptions appeared in less than 4% of all vacinees and fever (axillary temperature over 37.5°C) happened in less than 5% of cases. There is no statistic difference in the trials of this product with the reference vaccine (imported vaccine produced by multi-national pharmaceuticals).

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 hypodermically, not intradermally and never, under any circumstances, intravenously.
    a. Transfer the diluent in one of the vials with a syringe into the vial containing lyophilized vaccine. Shake well to ensure complete dissolution of the milky white crisp cake for use and transfer all the liquid back to the syringe.
    b. Apply 0.5ml solution for subcutaneously at the deltoid area of the upper arm.
    c. Alcohol and other disinfectant may inactivate the attenuated virus, thus the vaccine should be applied right after ensuring the complete evaporation of the disinfectant away from the skin.
5. Contact of any disinfectant with the vaccine of this product during opening and injecting of the vial and unclear label of glass vial.
6. Do not administer injection in condition of incomplete dissolution of this product, cracked glass vial and unclear label of glass vial.
7. It is recommended to use the vaccine as soon as it is reconstituted with SWFI
8. Avoid administration of other vaccines within 1 month following vaccination of this product.
9. Patients with leucocythemia, tumor or immunodeficiency should be restrainedly used 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 incase 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 appropriately contraceptive measure have been taken for at least 3 months following vaccination. It is not known whether the vaccine is excreted in human milk, because many drugs are 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 SWFI

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

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

Nature and Specification of the container
Kit for injection contains two 2mL vials made of borosilicate glass. The white fluey pellet of lyophilized vaccine is in one vial and the colorless diluent is in another vial.
This injection kit is used for 1 person in a single dose.

Instructions for use
The vaccine must be administered by a professional health care personnel or doctor.
The vaccine should be inoculated with the same syringe for other vaccines.
The vaccine must under no circumstances to be administered intravascularly or intramuscularly.
The vaccine is to be administered by subcutaneous injection only.

Manufactured for:
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SINCE 1946

NOVO
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