NEXIPOX PLUS®

Varicella Vaccine Live I.P., Pre-filled syringe.

Read all of this leaflet carefully before you or your child is vaccinated because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This vaccine has been prescribed for you or your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What NEXIPOX PLUS® is and what it is used for

NEXIPOX PLUS® is a live vaccine to help protect children, adolescent and adults against varicella zoster virus (chickenpox disease). Vaccines are used to protect against infectious diseases. **NEXIPOX PLUS®** can be administered to healthy subjects with 2 doses from 12 months of age, at least 3 months apart. After vaccination, the body's immune-activity against varicella can be generated for preventing the person from acquiring varicella infection.

2. What you need to know before you take NEXIPOX PLUS®

Contraindications:

a) Subjects with known hypersensitivity to any constituent of this product including neomycin.
b) Women during pregnancy.
c) Subjects suffering from serious diseases (acute or chronic infection), fever and any advanced immune disease.
d) Subjects treated with steroidal drug.
e) Subjects with a total lymphocyte count of less than 1200 per mm3 or presenting other signs of cellular immunodeficiency.
f) 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:

a) It is advisable to have a solution of epinephrine available in the case of anaphylactic reaction.
b) Generally speaking, it is advisable to keep the subject under medical supervision for 30 minutes following vaccination of this product.
c) 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.
d) Administered subcutaneously, not intra-dermally and never, under any circumstances, intravenously
   • Transfer the sterile diluent from the syringe into the vial containing lyophilized vaccine, shake well to ensure complete dissolution of the white fluey pellet before use.
   • Inject 0.5 ml reconstituted solution subcutaneously at the deltoid area of the upper arm.
e) Contact of any disinfectant with the vaccine of this product during opening and injecting of the vial should be avoided.
f) 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.
g) It is recommended to use the vaccine as soon as it is reconstituted with sterile diluent.
h) Avoid administration of other vaccines within 1 month following vaccination of this product.
i) Patients with leucocythemia, tumor or immunodeficiency should use the vaccine restrainedly under doctor's guidance.
j) 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

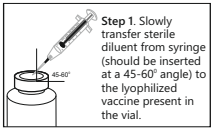
Not Known

3. How to use NEXIPOX PLUS®

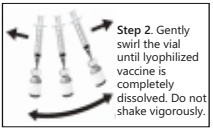
The vaccine must be administered by a professional health care personnel or doctor.
The vaccine should not be inoculated with the same syringe for other vaccines.
The vaccine must under no circumstances to be administered intravenously or intramuscularly.

The vaccine is to be administered by subcutaneous injection only.

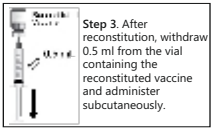
Instructions for reconstitution of the vaccine with the sterile diluent presented in a pre-filled syringe-



Step 1. Slowly transfer sterile diluent from syringe (should be inserted at a 45-60° 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:

a) Reconstitute the vaccine with the sterile diluent in the syringe and shake well to ensure complete dissolution of the white fluey pellet before use.
b) Inject the reconstituted vaccine, subcutaneously at the deltoid insertion area of the lateral aspect of the upper arm.
c) 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.
d) Contact with the disinfectant must be avoided.
e) **NEXIPOX PLUS**® should not be administered intra- dermally (ID) or intra-venously (IV). It is recommended to use the vaccine as soon as it is reconstituted.
f) DISCARD RECONSTITUTED VACCINE IF NOT USED WITHIN 30 MINUTES.

Dosage:

2 doses of varicella vaccine should be given from 12 months to 12 years of age, at least 3 months apart in healthy subjects.

4. Possible side effect

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

5. How to store NEXIPOX PLUS®

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

6. Contents of the pack and other information

Each 0.5ml of **NEXIPOX PLUS®** Contains:

Name of the Drug	**Varicella Vaccine (Live, Attenuated)**
Dosage form:	Freeze-dried injection (Subcutaneous)
Composition	
Name of Active Ingredient	Quantity
Oka strain	Not less than 3.3lg PFU
Name of Inactive Ingredient	
Sucrose	3.8mg
Trehalose	22.5mg
Sodium Glutamate	4.5mg
Urea	0.9mg
Arginine	0.9mg
Glucose	1.85mg
Human Albumin	5.0mg
Diluent	
Sterile Water for Injection	0.5ml

Nature and specification of the Pack:

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

You can help by reporting any side effects, you may get after vaccination to Novo Biological Pvt. Ltd. who is the importer of **NEXIPOX PLUS®** on 24X7 Toll-Free Number: 1800 309 0896 or by E-mail at drugsafety@novobiologicals.com.

For more information, read this Package Insert carefully.

Marketing Authorization Holder and Manufacturer:

NOVO —SINCE 1946— Novo
Medi Sciences Pvt. Ltd.
653/5, The Epicentre, 1301–1305, Waman Tukaram Patil Marg, Mumbai 400071, Maharashtra, INDIA.
By: Changchun BCHT Biotechnology Co.,Changchun High-tech Zone, Changchun, China.
Sales Office : 133 to 154, Jawahar co-op Ind, Kamothe, Navi Mumbai - 410209, Maharashtra, INDIA.
® Registered Trade Mark

NMSLN201507/NOV01