Live Attenuated Varicella Virus Vaccine

Varicella Vaccine-GCC inj.

Description

The vaccine is a lyophilized preparation of live attenuated Varicella virus and becomes a transparent, colorless or yellowish solution when reconstituted with the diluent supplied.

[Composition]

Each 1 vial contains (0.7mL, when reconstituted)

Active Ingredient		
Live attenuated Varicella virus	----------	NLT 1,400 PFU
Inactive Ingredient		
Sucrose	----------	25 mg
Glycine	----------	2.5 mg
Sodium L-glutamate hydrate	----------	0.55 mg
Gelatin	----------	12.5 mg
L-Cystein	----------	0.25 mg
Edetate Disodium	----------	0.25 mg
$Na_2HPO_4.12H_2O$	----------	q.s.
$NaH_2PO_4.2H_2O$	----------	q.s.
Annexed vial		
Water for Injection	----------	0.7mL

[Indication]

For prophylaxis of varicella

[Dosage and Administration]

After reconstitution with diluents supplied, inject a single dose of 0.5mL subcutaneously.

[Precaution]

1. Contraindications

Vacinnee needs to be interviewed and inspected for medical examination before injection, and if it is considered necessary, one's physical condition should be examined by auscultation and percussion, and injection shall not be conducted with the following conditions. If it is recognized that a vacinnee may be infected with varicella and if remarkable defect is not likely to be caused, injection may be done.

The vaccine is contraindicated to the individuals with:

1) Fever or malnutrition.
2) Patients in acute, incremental, or active stage of cardiovascular, renal or hepatic disorder, blood disorder, developmental disorder, or other disorders
3) Patients with untreated active tuberculosis.
4) Patients with febrile respiratory illness or who have been infected with active febrile illness.
5) Patients with severe illness.

6) History of anaphylaxis to this vaccine.
7) History of hypersensitivity to any component of this vaccine.
8) History of hypersensitivity to kanamycin and erythromycin.
9) History of fever, and allergic reactions such as generalized rashes and etc. within 2 days after vaccination.
10) History of spasm within 1 year prior to administration.
11) Cellular immunodeficiency (Can be diagnosed by lymphocyte counts, delayed type hypersensitivity (skin) test, and etc.)
12) Patients with malignant neoplasm, lymphoma, leukemia, or blood dyscrasia; which affects the bone marrow and lymphatic system
13) Primary, acquired immunodeficiency including immunosuppression, cell immunodeficiency hypogammaglobulinemia, dysgammaglobulinemia, associated with AIDS or clinical manifestation of human immunodeficiency virus infection.
14) Patients with a family history of congenital or inherited immunodeficiency (Do not administer vaccination until when the immunity is proved.)
15) Patients who take immunosuppressive drug
16) Pregnant woman or patients with possibility of pregnancy
17) Woman expecting to conceive within 2 months
18) Administration of other live vaccines (oral polio, measles, rubella, mumps, yellow fever and BCG vaccines) within 4weeks
19) Patients with the inadequate conditions to vaccinate
20) History of hypersensitivity to thimerosal

2. Special precautions

It has been reported that gelatin containing drugs or gelatin containing food is related to shock, anaphylactoid symptoms (hives, dyspnea, edema around the pips or larynx, and etc.). Accordingly, medical examination should be done thoroughly and observation after vaccination is highly recommended.

3. Undesirable Effects

1) In healthy adults and children, fever and/or rash may occur 1~3 weeks after vaccination. Such occurrences are temporary and conditions will diminish within a few days. Anaphylactoid symptoms (hives, dyspnea, edema around the lips or larynx, and etc.) may occur in rare cases.
2) Conditions of hypersensitivity such as rashes, hives, erythema, itchiness, fever, and etc. may occur in rare cases right after vaccination and until the next day.
3) Idiopathic Thrombocytopenic Purpura (ITP) may occur in rare cases (1/1,000,000). Purpura, Nasal hemorrhage, oral mucosa bleeding, and etc. may occur few days to 3 weeks after vaccination in common cases. Patients should consult with a doctor if such conditions arise.
4) In high-risk patient, papule and vesicular eruptions accompanied by fever may occur 14 to 30 days after vaccination. They tend to occur in about 20% of acute lymphatic leukemia patients.
5) Herpes zoster may occur in high risk patients, however, its incidence have not been more often than observed in naturally infected patients.
6) Local adverse events: Redness, swelling, and induration may occur at the injection site.
7) Body as a whole: Anaphylaxis may occur.
8) Blood: Thrombocytopenia may occur.
9) Nervous System: Encephalitis, Guillan-Barre Syndrome, transverse myelitis, Bell's

palsy, ataxia, and paraesthesia may occur.

10) Respiratory System: Pharyngitis may occur.
11) Skin: Steven Johnson's Syndrome, erythema multiforme, Henoch-Schonlein Syndrome, Secondary bacterial infections of skin and soft tissue including impetigo/cellulitis, and herpes zoster may occur.
12) The most frequently reported side effects are listed in order of decreasing frequency as below.

① Children under the age of 12
Upper respiratory disorder, cough, irritability/nervousness, fatigue, sleep disturbance, diarrhea, loss of appetite, vomit, otitis, diaper rash/contact rash, headache, malaise, abdominal pain, rash, nausea, eye complaint, chills, lymph node enlargement, myalgia, lower respiratory disorder, allergic reactions, neck stiffness, heat rash/prickly heat, arthralgia, eczema/ dry skin/dermatitis, constipation, itchiness. Rare cases of pneumonia and febrile seizure have been reported but causal relationship has not been established.

② Children above 13 years of age and adults
Upper respiratory disorder, headache, fatigue, cough, myalgia, sleep disturbance, nausea, diarrhea, neck stiffness, irritability/nervousness, lymph node enlargement, chills, eye complaint, abdominal pain, loss of appetite, arthralgia, otitis, itchiness, vomit, rash, constipation, lower respiratory disorder, allergic reactions, contact rash, herpes simplex/aphthous stomatitis.

4. General cautions

1) Check for unusual cloudiness, discoloration, particles, and etc. prior to use. DO NOT use the product if any of the indicated signs are noticed.
2) The vaccinees or their legal guardians should be informed to take a rest until the next day of vaccination and keep the injection site area clean. After vaccination, consult with a doctor immediately if high fever, convulsion, and etc. occur
3) Adequate treatment including epinephrine (1:1,000) should be followed immediately when an anaphylaxis or other allergic reaction occurs.
4) This vaccine contains gelatin. Consult with a doctor prior to vaccination since it has been reported that administration of gelatin is related to shock, anaphylactoid symptoms (hives, dyspnea, edema around the lips or larynx, and etc.), and etc. Observation after vaccination is highly recommended.

5. Interaction with other medicinal products and other forms of interaction

1) Vaccine should not be given for at least 5 months following blood or plasma transfusion and any immunoglobulin or Varicella zoster immunoglobulin (VZIG) administration. Patients with Kawasaki disease or idiopathic thrombocytopenic purpura (ITP) who had higher dose administration of gamma globulin than 200mg/kg, should postpone vaccination after more than 6months. Varicella vaccine will not be effective if subjects administer gamma globulin within 14 days of vaccination. Therefore, it is recommended that subjects get revaccinated 3 months following the first vaccination
2) Following vaccination, immunoglobulin including VZIG should not be given for 2 months unless more beneficial than vaccine.
3) Patients who have been vaccinated with other live vaccines (polio, measles, rubella, mumps, yellow fever, BCG, and etc.), generally use varicella vaccine after more than 4weeks following other live vaccines.
4) For 6 weeks following vaccination, do not use salicylate as Reye's syndrome has been

reported following the use of salicylate during wild-type Varicella infection.

6. Pregnancy and lactation

Nursing mother should be careful of use during lactation since certain viruses are secreted even though it is not known if varicella virus is secreted.

7. Pediatric Use

Safety and efficacy in infants below 1 year of age have not been established. Therefore, vaccination in infants below 1 year of age is not advisable.

8. Geriatric Use

Since elderly patients generally have low physiological function, vaccine should be administered with special care and vacinee should be monitored carefully.

9. Instructions for use and handling

1) Tools for injection should be sterilized by heat, high pressure steam, gamma-ray from ethylene oxide gas or cobalt 60, and then use them after cooling down to room temperature.
2) After sterilizing rubber stopper and its surroundings, extract the required amounts with the syringe. Do not tear off rubber and do not use in different container.
3) This vaccine should be reconstituted right before vaccination and after reconstitution, the vaccine should be used immediately.
4) Injection site generally should be humerus lateral side and sterilized by ethanol or tincture of iodine. Also, repeated injection at the same site should be avoided.
5) Check whether the end point of needle is inserted into blood vessel or not.
6) The needle of syringe must be used only once.

[Storage and Shelf life]

Store at 2-8℃ in hermetic container and protect from light.

The product may be used for 24 months from the date of manufacture.

[How supplied]

0.7ml/vial x 1, 5, 10 (Including attached diluent)

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