Registration No.: 1C 22/50 (N)

Importer / Manufacturer: Biogenetech Co., Ltd. / GC Biopharma Corp

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

VARICELLA VACCINE-GCC INJ.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 vial contains (0.7 mL, when reconstituted)

Live attenuated Varicella virus (MAV/06 strain)	NLT 1,400 PFU
Sucrose	25 mg
Glycine	2.5 mg
Sodium L-glutamate hydrate	0.55 mg
Gelatin	12.5 mg
L-Cysteine	0.25 mg
Edetate Disodium	0.25 mg
$Na_2HPO_4 12H_2O$	q.s.
$NaH_2PO_4 2H_2O$	q.s.
Annexed vial	
Sterilized water for injection (diluent)	0.7 mL

3. PHARMACEUTICAL FORM

The vaccine is a lyophilized preparation of live attenuated Varicella virus and becomes a slightly whitish or yellowish liquid with some whitish deposits when reconstituted with the diluent supplied.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For prophylaxis against Varicella in individuals aged 1 year or older

The vaccination is recommended in the subject who has no history of Varicella and meets the below criteria :

1. High risk patents predisposed to varicella infection.
2. In acute lymphatic leukemia patients who meet all 4 below criteria:
   - 2.1 Who are in remission from leukemia for at least 1 year.
   - 2.2 Who have no detectable antibodies to Varicella zoster virus by FAMA.
   - 2.3 Who have a positive response to mitogens in vitro.
   - 2.4 Who have more than $700/mm^3$ lymphocytes.
3. Subjects who have closely come in touch with the unvaccinated high risk patients (e.g., parents, siblings or medical and paramedical attendants of the high risk patients).
4. Susceptible subjects in closed community (e.g. hospital ward or dormitory) such as healthcare workers.
5. Women who want to be prevented during pregnancy and the vaccination shall be done before pregnancy.

4.2 Posology and method of administration

Inject a dose of 0.5 ml subcutaneously as following schedules.

- Children aged 1-12 years: The first dose shall be administered at 12-18 months. The second dose may be administered at 4-6 years.

In case of Varicella outbreak, the second dose of vaccine may be administered before 4 years of age, provided at least 3 months interval from the first dose.

In case the first dose is administered after 12-18 months of age, the second dose may be administered at 4 years of age or older but the interval between the first and second dose shall be 3 months at least.

- Person aged 13 years and older: Two doses of vaccine shall be administered with a minimum interval of 4 weeks between doses.

It is recommended that use immediately after reconstitution. If not possible, should be used within 30 minutes after reconstitution.

4.3 Contraindication

The vaccine is contraindicated to the individuals with:

- Fever or malnutrition
- Cardiovascular, renal or hepatic disorder
- History of hypersensitivity to kanamycin or erythromycin
- History of spasm within 1 year prior to administration
- Cellular immunodeficiency
- Pregnancy or willingness to conceive within 2 months
- Administration of other live vaccines (oral polio, measles, rubella, mumps and BCG vaccines) within 1 month
- History of hypersensitivity to any component of this vaccine
- Primary, acquired immunodeficiency including immunosuppression associated with AIDS or clinical manifestation of human immunodeficiency virus infection
- Children under 12 months of age
- Patients with acute myelocytic leukemia, T-cell leukemia or malignant lymphatic tumor.
- Patients who may be highly immunosuppressed due to radiotherapy or intensified treatment for leukemia.

4.4 Special warnings and precautions for use

Adequate treatment including epinephrine (1:1,000) should be followed immediately when an anaphylactoid reaction occurs.

The duration of protection from varicella infection after vaccination with varicella is unknown. Transmission of vaccine virus from vaccinees without a varicella-like rash has been reported but not confirmed. Therefore, vaccine recipients should avoid close associatin with susceptible high risk individuals for up to 6 weeks following vaccination, whenever possible. High-risk individuals include immunocompromised individuals and pregnant women without documented history of varicella or laboratory evidence of prior infection.

Nursing mother should be careful of use during lactation since certain viruses are secreted even though it is no known if varicella virus is secreted.

In case of administration of 6-mercaptopurine, other dosages should be discontinued for at least one week before vaccination and resumed at least one week after vaccination.

In case of emergency situations (e.g. passive immunization by varicella-zoster immunoglobulin), the vaccination should be done unless there are immunosuppressed symptoms. In such emergency cases, the vaccine should be administered within 72 hours after exposure to varicella.

Inject the vaccine immediately after reconstitution. Occasionally whitish deposits, normally originated from cells in manufacturing process, may be present in the reconstituted solution.

4.5 Interaction with other medical products and forms of interaction

Vaccine should not be given for at least 5 months following blood or plasma transfusion and any immunoglobulin or Varicella zoster immunoglobulin (VZIG) administration.

Following vaccination, immunoglobulin including VZIG should not be given for 2 months unless more beneficial than vaccine.

For 6 weeks following vaccination, do not use salicylate as Reye's syndrome has been reported following the use of salicylate during natural Varicella infection.

4.6 Pregnancy and lactation

The vaccine is contraindicated in pregnant women or a persons who has willingness to conceive within 2 months

4.7 Effects on the ability to drive and use machines

N/A

4.8 Undesirable effects

In high-risk patient, papule and vesicular eruptions accompanied by mild fever may occur 14 to 30 days after vaccination. They tend to occur in about 20% of acute lymphatic leukemia patients. Herpes zoster may occur in high risk patients, however, its incidence and severity have not been more serious than observed in naturally infected patients.

Common adverse events are injection site complaints (pain/soreness, swelling and/or erythema, rash, pruritus, hematoma, induration, stiffness): fever > 102°F (39°C) oral, Varicella like rash (generalized or injection site).

4.9 Overdose

N/A

5 PHARMACOLOGICAL PROPERTIES

5.4 Pharmacodynamic properties

N/A

5.5 Pharmacokinetic properties

N/A

5.6 **Preclinical safety data**

N/A

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose, Glycine, Sodium L-glutamate hydrate, Gelatin, L-Cysteine, Edetate Disodium, $Na_2HPO_412H_2O$, $NaH_2PO_42H_2O$, Water for injection

6.2 Incompatibilities

N/A

6.3 Shelf life

Maximun validity: 24 months form the date of manufacture.

6.4 Special precautions for storage

Store at 2-8°C. Avoid exposure to light.

6.5 Nature and contents of container

0.7 mL/vial x 1 (reconstituent vial annexed)

6.6 Special precautions for disposal and other handling
N/A

7 MARKETING AUTHORISATION HOLDER
Biogenetech Co., Ltd.
18 Soi Udomsuk 37, Sukhumvit 103 Rd., Bangjak, Prakanong, Bangkok, 10260 THAILAND

8 MARKETING AUTHORISATION NUMBER(S)
1C 25/50 (N)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
March 14, 2007

10 DATE OF REVISION OF THE TEXT
June 8, 2020