

GC FLU Multi inj.

Influenza Vaccine (Split virion, Inactivated)

[DESCRIPTION]

GC FLU Multi inj. (The product) is a vial containing colorless or slightly whitish liquid made by splitting and inactivating influenza virus cultured by inoculating in the allantoic cavity of embryonated egg in order to maintain antigenicity. Influenza virus antigen is inactivated with formaldehyde and this vaccine complies with the WHO recommendations for the 2021 Season.

[INDICATIONS]

Prophylaxis against Influenza

[DOSAGE & ADMINISTRATION]

An intramuscular injection of the following doses and immunization is necessary in every year at same volume.

- 1) 6-35 months old : A single dose of 0.25mL intramuscular injection
- 2) 3-8 years old : A single dose of 0.5mL intramuscular injection
- 3) 9 years and older : A single dose of 0.5mL intramuscular injection

The children younger than 9 years of age who have not been vaccinated or have not been infected by influenza should be vaccinated two doses at an interval of at least 4 weeks.

[COMPOSITION]

1mL contains,

Active Ingredient:

Purified Inactivated Influenza Virus Antigen	90µg
Purified Inactivated Influenza Virus Antigen Type A [A/Victoria/2570/2019 IVR-215(H1N1)]	30µg
Purified Inactivated Influenza Virus Antigen Type A [A/Hong Kong/2671/2019 NIB-121(H3N2)]	30µg
Purified Inactivated Influenza Virus Antigen Type B [B/Washington/02/2019]	30µg
Sodium chloride	8mg
Potassium chloride	0.2mg
Disodium hydrogen phosphate dihydrate	1.2mg
Potassium dihydrogen phosphate	0.2mg
Thimerosal	0.01w/v %
Water for injection	q.s.

[PRECAUTIONS FOR USE]

1. Contraindications

- Examine vaccinee by history taking and visual inspection and if necessary, by auscultation and percussion. Then, vaccination is prohibited when vaccinee is diagnosed as one of the following cases.
- 1) Person who showed anaphylaxis by the components of the product
 - 2) Person with hypersensitivity to egg, chicken, any other chicken component, and the product component.
 - 3) Person who showed the symptom of convulsion within 1 year before vaccination.
 - 4) Person who showed Guillain-Barre syndrome within 6 weeks from the previous influenza vaccination or person with neurological disorders.

2. Take special care

Please consult with your doctor, if you or your child are not expected to achieve targeted immune response after vaccination because of being treated with medicines affecting immune system or having immunodeficiency. The doctor will decide whether vaccination of your child is proper or not. Please inform your doctor, in case you or your child are planning to have a blood test during the next few days after vaccination because the vaccination may results in false positive blood test results in few cases. The vaccination does not mean full protection to vaccinee from virus infection like other vaccines.

3. Adverse reactions

- 1) There is the possibility of local reactions such as redness, swelling and pain, or systemic reactions such as fever, rigor, headache, fatigue and vomiting. But they usually disappear within 2-3 days.
- 2) Encephalomyelitis : In rare cases, acute diffuse encephalomyelitis (ADEM) may occur. Fever, headache, convulsions, dyskinesia and consciousness disorder usually occur within 2 weeks following the administration of the vaccine. When these symptoms are suspected, appropriate medical treatment should be available by diagnosis with MRI and so on.
- 3) Allergic reaction or anaphylactic shock may occur in very rare cases.
- 4) Transient disorders of systemic and local nervous system may rarely occur. And palsy, neuralgia, cerebral hemorrhage or inflammation of the nervous system (ex. Guillain-Barre syndrome) have been reported.
- 5) Safety of the product was evaluated regarding 226 children (6 months - under 18 years), 803 adults (18 years - under 60 years) and 173 elderly (60 years -), and the adverse events are as follows. 849(70.63 %) out of 1,202 subjects showed adverse events : Children 74.78%, adults 74.10% and elderly 49.13%. Most of them were solicited adverse events (68.55%), and unsolicited adverse events were 139(11.56%). Drug related adverse events were 48(3.99%)
- ① Adverse events which were collected for 6 days after vaccination are listed as below table.

		All subjects (N=1,202)		Children (N=226)		Adults (N=803)		Elderly (N=173)	
		Total	Moderate and Severe	Total	Moderate and Severe	Total	Moderate and Severe	Total	Moderate and Severe
Local Adverse events	Pain	46.9%	0.5%	50.0%	1.3%	50.6%	0.4%	26.0%	0.0%
	Tenderness	52.3%	1.2%	52.7%	2.2%	57.8%	1.0%	26.6%	1.2%
	Erythema/Redness	11.3%	2.6%	26.1%	7.1%	7.6%	1.5%	9.3%	1.7%
	Induration/Swelling	4.5%	1.0%	11.5%	3.1%	2.9%	0.6%	2.9%	0.0%
Systemic Adverse events	Fever	0.8%	0.3%	3.1%	1.3%	0.1%	0.0%	0.6%	0.6%
	Headache	17.6%	1.9%	9.7%	1.8%	20.7%	2.4%	13.3%	0.0%
	Malaise	10.8%	1.1%	9.3%	0.9%	12.3%	1.3%	5.8%	0.6%
	Shivering	8.8%	1.1%	5.8%	0.9%	10.0%	1.3%	7.5%	0.6%
	Fatigue	22.9%	2.1%	19.0%	1.3%	25.9%	2.2%	13.9%	2.3%
	Sweating	6.3%	0.8%	6.2%	0.9%	6.2%	1.0%	6.9%	0.0%
	Myalgia	17.5%	1.8%	13.7%	2.7%	20.2%	1.9%	9.8%	0.6%
	Arthralgia	4.1%	0.3%	3.1%	0.0%	4.1%	0.4%	5.2%	0.6%

- ② Serious adverse events were reported 5 subjects. Except for 1 case (convulsion), the rest were evaluated as 'not related'(acute convulsive abdominal pain : 1 case, atelectasis : 1 case), or 'possibly not related'(gastroenteritis : 2 cases, bronchitis : 1 case).
- ③ Adverse events were collected for 21 days after vaccination, and they were reported 139 subjects (11.56%) among 1,202 subjects. The most frequent events were respiratory adverse events (64 subjects, 5.32%), and all subjects who had experienced adverse events were recovered without sequelae. Adverse events of which relativity cannot be excluded from the product were 48 subjects (3.99%) as follows. (Occasionally : 0.1% ~< 5% ; Rare : < 0.1%)

· Respiratory System

Occasionally: Coryza, Rhinorrhoea, Throat sore, Pharyngitis, Rhinitis
Rare: Upper Respiratory tract infection, coughing, Bronchitis

· Gastro-Intestinal System

Rare: Gastroenteritis, vomiting, Diarrhoea, Nausea

· Central & Peripheral Nervous System

Occasionally: Dizziness
Rare: Cramps legs, Migraine, Muscle contractions involuntary

· Skin & Appendages

Occasionally: Pruritus
Rare: Urticaria

· Vision Disorder

Rare: Abnormal sensation in eye, Asthenopia

· Metabolic and Nutritional disorder

Rare: Edema uvula

· White Cell and Rest Disorders

Rare: WBC abnormal nos.

· Psychiatric Disorders

Rare: Sleep disorder

· Local and systemic adverse events

Occasionally: Injection site pruritus, Swelling and Pruritus

Rare: Injection site erythema, Syncope, Fatigue, Pallor

· Cardiovascular disorder

Rare: Palpitation

4. General precautions

- 1) Advise the vaccinee or their guardians that the vaccinee should keep equilibrium, keep the injection site clean, and when the symptoms of high fever, convulsion appear, they should consult a physician quickly.
- 2) Antibody reaction cannot be sufficient in endogenous or iatrogenic immune deficient patients.
- 3) Influenza should be vaccinated before prevailing. Vaccination can be delayed according to epidemiological situation.
- 4) Influenza should be vaccinated with the influenza vaccines produced with current-year recommended strains.

5. Interaction with other medicinal products

- 1) There is no data or study on co-administration of the product with other vaccines. If co-administration is inevitably required, injection site should be different. It should be noted that the adverse events may be increased.
- 2) Immunization can be affected by concomitant immunosuppressive therapy or an existing immunodeficiency.
- 3) False positive (verified using Western Blot technique) ELISA serologic tests for HIV-1, Hepatitis C, and especially HTLV-1 may occur following influenza vaccination. These transient false-positive results may be due to cross-reactive IgM elicited by the vaccine.
- 4) Advise the vaccinee or their guardians that the vaccinee should keep equilibrium, keep the injection site clean, and when the symptoms of high fever, convulsion appear, they should consult a physician immediately.
- 5) Following medicinal products may cause interaction with the product
 - ① Medicinal products in order to control epilepsy or paroxysmal (Phenytoin, carbamazepine, Phenobarbitone)
 - ② Theophylline ③ Warfarin ④ Immune globulin
 - ⑤ Immune inhibitory agents (corticosteroid, Cyclosporine, anticancer drug(including radiation therapy) etc.)

6. Administration for pregnant or lactating woman

For pregnant women or women considered to be pregnant, please inform this to your doctor or pharmacist before vaccination. The vaccination is acceptable during period of pregnancy. Relatively larger safety data are obtained from second and third trimester of pregnancy to that of first trimester, and data collected from worldwide shows that fetus and pregnant mother did not experience any adverse reaction caused by vaccination. The vaccination during the breast-feeding may be acceptable. Your doctor or pharmacist will be able to decide whether the vaccination is recommendable for you. Please consult with your doctor or pharmacist before vaccination. WHO recommends "For countries considering the initiation or expansion of programmes for seasonal influenza vaccination, pregnant women should have the highest priority. Pregnant women should be vaccinated with TIV at any stage of pregnancy. This recommendation is based on evidence of a substantial risk of severe disease in this group and evidence that seasonal influenza vaccine is safe throughout pregnancy and effective in preventing influenza in the women as well as in their young infants, in whom the disease burden is also high. (WHO Weekly Epidemiological Record, 23 November 2012, 87th year, No. 47, 2012, 474)"

7. Precautions in administration

- 1) Before use check this product visually for particles or discoloration. If either is present, do not use.
- 2) Device used for vaccination should be cooled to room temperature after being sterilized using dried heat, high-pressure steam, ethylene oxide gas or gamma rays emitted from Cobalt-60.
- 3) After sterilization of the cap and its surroundings using ethanol, inject the needle into the container and withdraw a required amount into the syringe. Be careful not to cause contamination. Do not take off the cap and it should not be transferred to another container.
- 4) The injection site is usually lateral upper arm and disinfected with ethanol or tincture of iodine. Repeated injections at the same site should be avoided.
- 5) Intravenous administration is prohibited. 6) The tip of needle should not penetrate blood vessel.
- 7) Do not mix with other vaccines in same syringe. 8) New needle and syringe should be used for each vaccinee.

8. Precautions in handling

- 1) Do not use if the vaccine has been frozen.
- 2) The vaccine should be shaken well and mixed homogeneously before use.
- 3) Multi dose vials of GC FLU, which one or more doses of vaccine have been used during an immunization session, may be used in subsequent immunization sessions for up to 28 days if following conditions are met.
 - ① The vaccines are stored under appropriate cold chain conditions between use (2-8°C).
 - ② The vaccine vial septum has not been submerged in water.
 - ③ Aseptic technique has been used to withdraw all doses.

9. Miscellaneous

The used strain and unit are included in this leaflet.

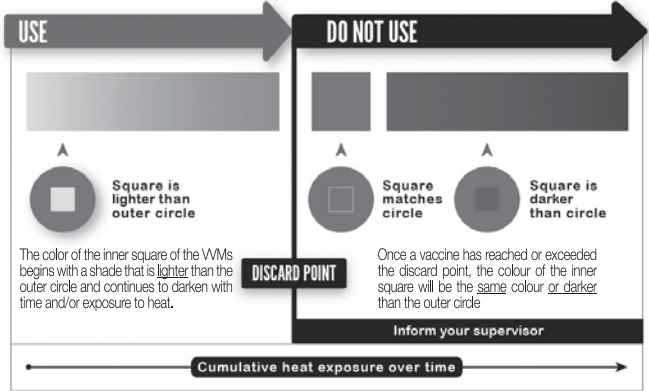
10. Storage

Store at 2-8°C without freezing in hermetic container and protect from light.
Shelf life: 12 months from the date of manufacture

11. How supplied

5mL/vial x In-house packing unit

The Vaccine Vial Monitors (VVM) are on the label of GCFLU Multi inj. attached to the vial body. The color dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.



The interpretation of the VVM is simple. Focus on the central square. Its color will change progressively. As long as the color of this square is lighter than the color of the circle, then the vaccine can be used. As soon as the color of the central square is the same color as the circle or of a darker color than the circle, then the vial should be discarded.



GC Pharma

Green Cross Corporation
40, Sandan-gil, Hwasun-eup, Hwasun-gun,
Jeollanam-do, Korea