120 x 260mm(2p) K

SK bioscience

SKYCellflu®

Trivalent Solution for Injection in Prefilled Syringe 0.5mL and 0.25mL

Influenza vaccine, surface antigen, inactivated, prepared in cell cultures **Intramuscular Inj.**

【Composition】

· Each 0.5 mL prefilled syringe contains:

Active ingredients:

Purified inactivated influenza virus surface antigen [A/Michigan/45/2015, NYMC X-275(H1N1)] (In-house) ····· 15μg
Purified inactivated influenza virus surface antigen [A/Singapore/INFIMH-16-0019/2016, IVR-186 (H3N2)] (In-house)····· 15μg
Purified inactivated influenza virus surface antigen [B/Maryland/15/2016] (In-house) ····· 15μg

Stabilizers:

Magnesium chloride hexahydrate (Ph.Eur.) ····· 0.050mg
Calcium chloride dihydrate (Ph.Eur.) ····· 0.067mg

Excipients: Sodium chloride, Potassium chloride, Potassium dihydrogen phosphate, Disodium phosphate dihydrate

Solvent: Water for injection (Ph.Eur.) ····· q.s.

Supplement: Disposable needle (25G×5/8(0.5×16mm)) (In-house) ····· 1ea

· Each 0.25 mL prefilled syringe contains:

Active ingredients:

Purified inactivated influenza virus surface antigen [A/Michigan/45/2015, NYMC X-275(H1N1)] (In-house) ····· 7.5μg
Purified inactivated influenza virus surface antigen [A/Singapore/INFIMH-16-0019/2016, IVR-186 (H3N2)] (In-house)····· 7.5μg
Purified inactivated influenza virus surface antigen [B/Maryland/15/2016] (In-house) ····· 7.5μg

Stabilizers:

Magnesium chloride hexahydrate (Ph.Eur.) ····· 0.025mg
Calcium chloride dihydrate (Ph.Eur.) ····· 0.033mg

Excipients: Sodium chloride, Potassium chloride, Potassium dihydrogen phosphate, Disodium phosphate dihydrate

Solvent: Water for injection (Ph.Eur.) ····· q.s.

Supplement: Disposable needle (25G×5/8(0.5×16mm)) (In-house) ····· 1ea

【Description】 Clear or slightly opalescent liquid contained within colorless and transparent prefilled syringe.

【Pharmacodynamics】 Seroprotection is generally obtained within 3 weeks. The duration of postvaccinal immunity to homologous strains or to stains closely related to the vaccine strains varies but is usually 6-12 months.

【Indications】 Active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine, for adults and children 6 months of age and older.

【Dosage and administration】

Following dose is administered via intramuscular injection, and same dose is repeated once annually.

Age	Vaccination Status	Dose
Aged 6 months through 35 months of age	Have not been previously vaccinated with influenza vaccine or infected	Two doses of 0.25 mL injection. Note: Second dose should be administered after an interval of at least 4 weeks
	Have been previously vaccinated with influenza vaccine	One dose of 0.25 mL as a single injection
Aged 36 months through 8 years of age	Have not been previously vaccinated with influenza vaccine or infected	Two doses of 0.5 mL injection. Note: Second dose should be administered after an interval of at least 4 weeks
	Have been previously vaccinated with influenza vaccine	One dose of 0.5 mL as a single injection
Aged 9 years and older	Not applicable	One dose of 0.5 mL as a single injection

【Precautions for use】

1. Do not administer SKYCellflu® to the following individuals.

If deemed necessary after a medical interview and visual inspection, examine the subject's health condition further using methods such as auscultation and percussion. Do not administer the vaccine to subjects with following conditions. As an exception, the vaccine may be administered to subjects who are at risk of possible influenza infection and determined to have no likelihood of developing serious disabilities due to the administration of the vaccine.

1) Hypersensitivity reaction to active ingredient and/or any other ingredient (including formalin) in SKYCellflu®
2) Febrile disease or acute infection
3) History of severe hypersensitivity reaction and/or convulsive symptom to previous influenza vaccination
4) History of Guillain-Barre syndrome or other neurological disorder within 6 weeks of previous influenza vaccination
5) Fever
6) Cardiovascular disease, renal disease, or hepatic disease in acute, exacerbation, or active phase
7) Acute respiratory disease or other active infection
8) History of anaphylaxis reaction to any ingredient in SKYCellflu®
9) History of suspected allergic reaction, including systemic rash, to previous vaccination
10) Other medical conditions that are diagnosed to be inappropriate for administration of SKYCellflu® vaccine.

2. Administer SKYCellflu® with caution to the following individuals.

1) Pregnant women or women of child-bearing potential
2) Patients with chronic cardiovascular or respiratory disease or patients with diabetes mellitus may experience significant exacerbation of existing disease upon influenza infection, and thus may receive vaccination with caution, as necessary.
3) As with other intramuscular injection, patients with bleeding disorder such as hemophilia and thrombocytopenia or patients on anticoagulant therapy should not receive SKYCellflu® unless the potential benefit outweighs the risk of administration. If the decision is made to administer SKYCellflu® in such persons, it should be administered with caution to avoid the risk of hematoma formation following injection

3. Adverse reactions

1) Local reaction: adverse reactions including injection site tenderness, pain, erythema/redness, and induration/swelling may occur; these reactions usually disappear instantly.
2) Systemic reaction: systemic reactions including myalgia, fatigue/malaise, headache, diarrhea, and vomiting may occur after vaccination; these reactions usually disappear within 3-4 days.
3) Encephalomyelitis: rarely, acute disseminated encephalomyelitis (ADEM) is reported. Fever, headache, convulsion, motor disorder, cognitive disorder, etc. may occur generally within days to 2 weeks after vaccination. In a case of suspected ADEM, diagnosis with MRI and proper intervention should be instituted.
4) Very rarely, allergic reaction to anaphylaxis may occur.
5) Temporary disorder of systemic and/or local neural network may occur. Sensitivity to stimulus or pain may be abnormal. Vascular, cerebral, or neuronal inflammation (e.g., Guillain-Barre syndrome) resulting in paralysis, neuropathic pain, bleeding, and internal bleeding has been reported.
6) Safety of SKYCellflu® was assessed in a study with 301 pediatric and adolescent subjects 6 months through 18 years of age, and 1,095 adult 19 through 59 years of age and followings were reported for adverse reactions.724 out of 1,396 (51.86%) subjects developed adverse reactions after vaccination. The incidence was 44.85% in pediatric and adolescent subjects 6 months through 18 years of age, 59.10% in adult subjects 19 through 59 years of age, and 31.43% in subjects ≥60 years of age.

① Adverse reactions observed during the 7–day period after SKYCellflu® vaccination are shown below.

		Total (N=1,396)	6 months through 18 years of age (N=301)	19 through 59 years of age (N=885)	≥60 years of age (N=210)
Local reaction	Tenderness	26.36%	7.64%	36.16%	11.90%
	Pain	29.51%	30.56%	32.43%	15.71%
	Erythema/redness	8.31%	15.28%	6.55%	5.71%
	Induration/swelling	3.87%	9.97%	2.37%	1.43%