Description	SKYCellfluQIVPFS_PI_(Malaysia)
Color	K
Size(mm)	W220 X L200
Folding Size(mm)	W110 X L51

1P

FSA06AF02

pharmaniaga®

SK bioscience

SKY Cellflu Quadrivalent® prefilled syringe

Influenza vaccine, surface antigen, inactivated, prepared in cell cultures

Intramuscular Inj.

48mm

8X8mm
아이마크

【Composition】 Each 0.5mL prefilled syringe contains:

Active ingredients:

Purified inactivated influenza virus surface antigen [A/Switzerland/6849/2025 (IVR-278) (H1N1)] (In-house) ····· 15μg
Purified inactivated influenza virus surface antigen [A/Singapore/GP20238/2024 (IVR-277) (H3N2)] (In-house) ····· 15μg
Purified inactivated influenza virus surface antigen [B/Michigan/01/2021] (In-house) ····· 15μg
Purified inactivated influenza virus surface antigen [B/Phuket/3073/2013] (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

【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 8 years	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 Quadrivalent® 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 Quadrivalent®
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 Quadrivalent®
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 Quadrivalent® vaccine.

2. Administer SKYCellflu Quadrivalent® 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 any bleeding disorder, such as hemophilia or thrombocytopenia, or patients on anticoagulant therapy should not receive SKYCellflu Quadrivalent® unless the potential benefits outweigh the risk of administration. If the decision is made to administer SKYCellflu Quadrivalent® 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 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 Quadrivalent® was assessed in a study with 449 children 6 months through 35 months of age, 255 pediatric and adolescent subjects 3 through 18 years of age, and 802 adults ≥ 19 years of age, and followings were reported for adverse reactions. 701 out of 1,506 (46.55%) subjects developed adverse reactions after vaccination. The incidence rate was 50.11% in children 6 through 35 months of age, 46.27% in pediatric and adolescent subjects 3 through 18 years of age, 49.00% in adult 19 through 59 years of age, and 26.14% in subjects ≥ 60 years of age.

① Solicited adverse reactions observed during the 7-day period after SKYCellflu Quadrivalent® vaccination are shown below.

		Total (N=1,506)	6 through 35 months of age(N=449)	3 through 18 years of age(N=255)	19 through 59 years of age (N=649)	≥ 60 years of age (N=153)
Local reaction	Tenderness	25.68%	20.27%	37.68%[1]	32.20%	8.50%
	Pain	24.77%		30.59%	29.28%	9.15%
	Erythema/redness	14.54%	27.39%	19.61%	6.47%	2.61%
	Induration/swelling	6.11%	10.69%	11.37%	2.16%	0.65%
Systemic reaction	Myalgia[2]	14.10%	-	11.37%	16.02%	10.46%
	Fatigue/malaise[3]	11.61%	-	7.77%	13.71%	7.84%
	Headache[2]	7.57%	-	5.49%	8.94%	5.23%
	Diarrhea[4]	1.84%	-	0.00%	2.31%	0.65%
	Vomiting[4]	0.57%	-	0.00%	0.62%	0.65%
	Whining/annoyed[5]	12.60%	16.26%	3.76%	-	-
	Somnolence/exhausted[5]	10.39%	12.69%	4.84%	-	-
	Fever	2.39%	7.57%	0.39%	0.15%	0.00%
	Arthralgia[6]	2.15%	-	2.15%	-	-

[1]Reported in subjects ≥12 years of age(N=69). [2]Reported in subjects ≥3 years of age(N=1,057). [3]Reported in subjects ≥5 years of age(N=1,008). [4]Reported in subjects ≥12 years of age(N=871). [5]Reported in subjects <12 years of age(N=635). [6]Reported in subjects ≥3 and <12 years of age(N=186).

② Unsolicited adverse reactions observed during the 21-day (adults) or 28-day (children and adolescents) period after SKYCellflu Quadrivalent® vaccination were reported in 35 out of 1,506 (2.32%) subjects. Adverse reactions related to respiratory system in 14 subjects (0.93%) was most frequently observed. Adverse reactions observed during the study period are shown below. (Uncommon: 0.1 to <5%, Rare: <0.1%)

Category	Frequency	
	Uncommon	Rare
Respiratory system	Nasopharyngitis, Upper respiratory tract infection, Rhinorrhea	Pharyngitis, Cough, Herpangina
Gastrointestinal disorders	Diarrhea	Dyspepsia, Vomiting, Decreased appetite
General disorder and administration site condition	Pyrexia	Injection site pruritus/Injection site warmth
Skin and subcutaneous tissue	Rash	Eczema, Viral rash
Musculoskeletal system	Myalgia	
Nervous system		Paresthesia
Sensory organ		Eye discharge

③ 20 out of 1,506 subjects developed 21 serious adverse events (449 subjects with 0.5mL for 6 to 35 months after birth were followed by 1 month after vaccination) by 6 months after administration of SKYCellflu Quadrivalent® vaccine (2 cases of gastroenteritis, 2 cases of pneumonia, 2 cases of mycoplasma pneumonia, 1 case of acute bronchitis, 1 case of acute stomachache, 1 case of acute pharyngitis, 1 case of bacterial pneumonia, 1 case of bronchopneumonia, 1 case of viral induced wheeze, 1 case of acute gastroenteritis, 1 case of diverticulitis, 1 case of wrist fracture, 1 case of tooth abscess, 1 case of benign prostatic hypertrophy, 1 case of deviated septum, 1 case of benign neoplasm of breast, 1 case of cerebral hemorrhage, 1 case of enuresis) and all of which were concluded to be unrelated to SKYCellflu Quadrivalent® except 1 case of acute pharyngitis.

7) Post Marketing Experience

① During this 4-year post marketing surveillance (PMS), among 655 subjects on adults aged 19 years and older, adverse events were reported by 6.87% (45/655 subjects, 69 cases) regardless the causal relationship with the vaccine. No serious adverse events or serious adverse drug reactions were reported. In addition, unexpected adverse events and unexpected adverse drug reactions are shown below according to its frequency.

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Uncommon (0.1 to <5%)		Unexpected adverse events regardless the causal relationship with the vaccine were reported by 1.68% (11/655 subjects, 16 cases)	Unexpected adverse drug reactions that causal relationship with the vaccine could not be excluded were reported by 0.76% (5/655 subjects, 6 cases)
	Respiratory, thoracic, and mediastinal disorders	Cough, Oropharyngeal pain, Respiratory disorder, Rhinitis allergic	Cough, Oropharyngeal pain
	Nervous system disorders	Dizziness	Dizziness
	General disorders and administration site conditions	Influenza like illness	Influenza like illness
	Infections and Infestations	Acute sinusitis, Tonsillitis, Tracheobronchitis	
	Gastrointestinal disorders	Gastritis	
	Injury, poisoning and procedural complications	Contusion, Skin abrasion, Thermal burn	

② During 4-year PMS, among 603 subjects on children and adolescents aged 3 to 18 years, adverse events were reported by 18.57% (112/603 subjects, 222 cases) regardless of the causal relationship with the vaccine. No serious adverse events or serious adverse drug reactions were reported. In addition, unexpected adverse events and unexpected adverse drug reactions are shown below according to its frequency.

		Unexpected adverse events regardless of the causal relationship with the vaccine were reported by 5.47% (33/603 subjects, 44 cases)	Unexpected adverse drug reactions that causal relationship with the vaccine could not be excluded were reported by 0.50% (3/603 subjects, 3 cases)
Not common (≥0.1% to <1%)	*General disorders and administration site conditions*	Asthenia	Asthenia
	Infections and infestations	Conjunctivitis, Bronchiolitis, Croup infectious, Impetigo, Laryngitis	
	Gastrointestinal disorders	Enteritis, Constipation	
	Respiratory, thoracic, and mediastinal disorders	Nasal obstruction, Rhinitis allergic	
	Skin and subcutaneous tissue disorders	Urticaria	
Common (≥1% to <10%)	*Infections and infestations*	Bronchitis	

③ During PMS performed on 612 subjects for infants and toddlers aged 6 months to 35 months (from 12 June 2020 to 11 June 2024), adverse events were reported by 37.58% (230/612 subjects, 635 cases) regardless of the causal relationship with the vaccine. Among them, serious adverse events were reported by 0.98% (6/612 subjects, 6 cases) while no serious adverse drug reactions were reported. In addition, serious adverse drug reactions that causal relationship with the vaccine could not be excluded and unexpected adverse drug reactions are shown below according to its frequency.

		Serious adverse drug reactions were reported by 0% (0/612 subjects, 0 case)	Unexpected adverse drug reactions were reported by 0.98% (6/612 subjects, 6 cases)
Not common (≥0.1% to <1%)	*Investigations*		Body temperature decreased
	General disorders and administration site conditions		Vaccination site rash
	Skin and subcutaneous tissue disorders		Dermatitis contact, Pruritus, Erythema

④ At the point of re-examination, integrated assessment of adverse events in SKYCellflu was conducted from re-examination reports to MFDS and adverse events from spontaneous reports compared with all reported events in all licensed vaccines in Korea (1989-March 31, 2020). Among the statistically significant adverse events reported on this vaccine compared to those reported on all other vaccines the following are newly identified. However, this does not mean that the causal relationship between the component of this vaccine and the following adverse events has been proved.

• General disorders and administration site conditions: Chills, Vaccination site bruising

4. General precautions

1) Instruction should be provided to the vaccine recipient or caregiver to have a rest on the day of vaccination and next day, to maintain the injection site clean, and to immediately seek medical attention if symptoms such as fever and convulsion develop after vaccination.
2) Antibody response may be insufficient in patients with inherited or iatrogenic immunodeficiency.
3) Influenza vaccine should be administered before influenza outbreaks. Vaccination may be delayed depending on epidemiological situation.
4) Influenza vaccine should be administered annually using a new vaccine composed with strains recommended each year.
5) SKYCellflu Quadrivalent® can prevent disease caused by influenza virus only, and does not prevent infection caused by other sources which show similar symptoms as influenza.
6) As with other injectable vaccine preparations, appropriate emergency intervention should be prepared for potential anaphylaxis response after administration of the vaccine.
7) Syncope may occur after or even before vaccination as a psychological reaction to injection needle. Appropriate measures should be taken to prevent injury from syncope.

5. Interaction

1) Concurrent immunosuppressive therapy or immunodeficiency may affect immunological response to the vaccine.
2) Co-administration of SKYCellflu Quadrivalent® with other vaccines has not been studied. If concomitant vaccination cannot be avoided, injections should be administered on different sites, and the patients should be informed of possible increases in the severity of the adverse effects due to the co-administration.
3) False positive response has been reported from the serum test after influenza vaccination, which measures antibody against HIV1, HCV, and particularly HTLV1 using ELISA assay (false positivity confirmed with Western Blot technique). Such temporary false positive result is attributed to IgM reaction from the vaccination.
4) Immunosuppressive therapy (radiotherapy, anti-metabolic agent, alkylating agent, cytotoxic agent, and supraphysiological doses of corticosteroid) may reduce the immunological response to influenza vaccine.

6. Overdose

There is no specific information on overdose of SKYCellflu influenza vaccine.

7. Use in pregnant women and nursing mothers

1) Safety of SKYCellflu Quadrivalent® has not been evaluated in pregnant women. Direct and/or indirect adverse effect related to reproduction and developmental toxicity was not observed in animal studies. SKYCellflu Quadrivalent® should be administered to pregnant women or women of child-bearing potential only if clearly needed.
2) Safety of SKYCellflu Quadrivalent® has not been evaluated in breastfeeding women. Since it is not known whether SKYCellflu Quadrivalent® is excreted in breast milk, caution should be exercised when SKYCellflu Quadrivalent® is administered to a nursing mother.

8. Instruction for administration

1) Inspect the vaccine visually for any particulate matter or change in physical appearance prior to administration.
2) Before administering a dose of vaccine, shake the vaccine well until colorless or opalescent solution is achieved. Do not use the vaccine in case any abnormalities are observed.
3) Remove the vaccine from the refrigerator and allow reaching room temperature before use. Shake well to achieve homogenous solution before use (storage condition is 2~ 8°C refrigeration).
4) Upon long-term storage, vaccine may show slight aggregation. This does not indicate abnormal quality, and is easily resuspended by shaking the vaccine.
5) Do not administer SKYCellflu Quadrivalent® via intravenous injection.
6) Lateral upper arm is the typical administration site, and should be disinfected with ethanol or iodine tincture before the administration. In addition, it is advised to avoid repeating vaccination at the same site.

9. Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

10. Precautions for storage and handling

1) Store SKYCellflu Quadrivalent® refrigerated at 2~8°C away from light. Do NOT freeze.
2) Do not use the vaccine if the contents have been frozen, because it may cause changes in product quality.

11. Others

Unit and name of the virus strains recommended annually and used for this vaccine production are specified in【Composition】of this package insert.

【Storage】 Keep refrigerated at 2~8°C in a hermetic container away from light. Do NOT freeze.

【Expiration date】 As marked separately on the primary container.

【Packaging units】 0.5mL/prefilled syringe. Supplied in pack size of 1 or 10. *Not all pack sizes may be marketed.*

Revised on 20 Jan 2026

Product Registration Holder
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