SUMMARY OF PRODUCT CHARACTERISTICS
(SPC)

1. NAME OF THE MEDICINAL PRODUCT

AdimFlu-S Influenza Vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This vaccine, a clear or slightly whitish opaque liquid, contains purified influenza virus HA antigen.

Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of the following strains*:

A/H1N1 : 15 micrograms HA** per 0.5 ml dose

A/ H3N2 : 15 micrograms HA** per 0.5 ml dose

B (Victoria or Yamagata lineage) : 15 micrograms HA** per 0.5 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks

** haemagglutinin

3. PHARMACEUTICAL FORM

Suspension for injection in pre-filled syringe.

A clear or slightly whitish opaque liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This vaccine is intended for use in the prevention of influenza.

4.2 Posology and method of administration

(1) For children of age 6 months to age < 3, one dose of 0.25 mL of vaccine is injected.

(2) For children of age ≥ 3 and for adults, one dose of 0.5 mL of vaccine is injected. For children of age < 9 previously unvaccinated with any seasonal flu vaccine, two doses should be administered. Each dose should be administered at least 4 weeks apart.

This vaccine is administered subcutaneously or intramuscularly.

4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients listed in Section 6.1 or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), formaldehyde and polysorbate 80.

Occurrence of Guillain-Barre syndrome (GBS) within weeks after receiving this vaccine previously

Vaccination should be postponed in case of febrile illness or moderate or severe acute

disease.

4.4 Special warnings and precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

AdimFlu-S should under no circumstances be administered intravascularly.

As with other vaccines administered intramuscularly, the vaccine should be administered with caution to subjects with thrombocytopaenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent injury from fainting and manage syncopal reactions.

As with any vaccine, vaccination with AdimFlu-S may not protect 100% of susceptible individuals.

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

4.5 Interaction with other medicinal products and other forms of interaction

- Interactions: with relation to immuno-suppressants such as Cyclosporin. For individuals using immuno-suppressants, especially for long term or large quantity use, the expected effect of this vaccine may not be achieved.
- There are no data on co-administration of AdimFlu-S with other vaccines.
- However, if co-administration with another vaccine is considered, immunization should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.
- Following influenza vaccination, false-positive serology test results may be obtained by the ELISA method for antibody to human immunodeficiency virus-1 (HIV-1), hepatitis C virus and, especially, HTLV-1. In such cases, the Western blot method is negative. These transitory false-positive results may be due to IgM production in response to the vaccine.

4.6 Fertility, pregnancy and lactation

Pregnancy

Inactivated influenza vaccines can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of inactivated

influenza vaccines do not indicate any adverse foetal and maternal outcomes attributable to the vaccine.

Breastfeeding

AdimFlu-S may be used during breastfeeding.

Fertility

No fertility data are available.

4.7 Effects on ability to drive and use machines

AdimFlu-S has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

(1) During clinical trials of AdimFlu-S, the following side effects have been observed:

Adverse reactions are listed according to the following frequencies:

Very common: ≥ 1/10

Common: ≥ 1/100 to < 1/10

Uncommon: ≥1/1,000 to < 1/100

The safety profile presented below is based on data from the clinical trial in healthy subjects aged over 18 years

System Organ Class	Very common	Common	Uncommon
General disorders and administration site conditions	Pain/Soreness	Swelling, Redness, Decreased limb mobility	Ecchymosis
Respiratory, thoracic and mediastinal disorders		Nasal congestion, Cough, Sore throat	
Musculoskeletal and connective tissue disorders		Muscle aches, Malaise	
Nervous system disorders		Headache	
Eye disorders		Eye redness	
Gastrointestinal disorders		Nausea, Vomiting	
Skin and subcutaneous tissue disorders			Facial edema

(2) The following adverse reactions occurred after the vaccine came on the market:

Blood and lymphatic system disorders: Thrombocytopenia, Lymphadenopathy

Gastrointestinal disorders: Abdominal pain, Dysphagia, Anhepatia

Metabolism and nutrition disorders: Lack of appetite

General disorders and administration site conditions: Malaise, Influenza-like

symptoms, Severe welling

Musculoskeletal and connective tissue disorders: Arthritis, Back pain, Pain of limbs

Nervous system disorders: Neurologic abnormality (Facial palsy symptoms), Dizziness, Somnolence, Syncope,Nerves pain, Abnormal gait, Facial palsy, Hypesthesia, Dysesthesia, Seizure, Guillain-Barre syndrome (GBS), shake, Acute disseminated encephalomyelitis (ADEM)

Vascular disorders: Pale, Hot flashes, Vasculitis, Transient renal involvement (very rare)

Hypersensitivity: Shock, Asthma, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Rash

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC code: J07BB02.

An antibody immune response is generally induced within 3 weeks. The duration of postvaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually more than 6 months.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data revealed no special hazard for humans based on conventional studies of repeat dose and local toxicity, and reproductive and developmental toxicity studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride (NaCl),

Disodium hydrogen phosphate (Na_2HPO_4),

Potassium dihydrogen phosphate (KH_2PO_4)

Water for injection (WFI)

6.2 Incompatibilities

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

6.3 Shelf-life

One year.

6.4 Special precautions for storage

Store this vaccine in a cool and dark place (2~8℃). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

6.5 Nature and contents of container

Syringe: One-dose prefilled syringe (0.5ml)

This vaccine is filled in syringe (type I glass) with plunger stopper (chlorobutyl rubber) with needle.

6.6 Special precautions for disposal and other handling

- Handling of the vaccine:
  1. Do not freeze the product. If the vaccine is frozen by mistake, discard it due to the possibility of deterioration.
  2. After taking out from the refrigerator, this vaccine has to be warmed up to the room temperature and mixed well before use.
  3. Check the vaccine for abnormal cloudiness, color, foreign material and other anomaly; if any of these is present, discard the product.
  4. Due to an absence of clinical data to support the interchangeability of influenza vaccines, one should not complete the vaccination course with different brands of seasonal flu vaccines.
- Handling of the product in prefilled syringe packaging:
  1. Each syringe is aseptically packaged and for single dose only. Do not use the medicament contained inside once the needle structure has been destroyed or broken.
  2. If the vaccination is to be given to a child younger than the age of 6, only half of the dose (i.e., 0.25 mL) of a pre-filled 0.5 ml syringe is required. Discard half of the content of the syringe and use the rest for injection.

7. MARKETING AUTHORIZATION HOLDER

Adimmune Corporation

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8. MARKETING AUTHORIZATION NUMBER(S)

Number of product-license Taiwan: DOH-BM-000113

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

First authorization: October 30, 2001

Renewal of authorization: October 30, 2016

10. DATE OF REVISION OF THE TEXT

October 12, 2017