Summary of Product Characteristics

1. Name of the medicinal product

Influvax Tetra
Inactivated Influenza Vaccine (Split Virion) BP
Suspension for injection in Prefilled Syringe, 0.5 ml

2. Qualitative and quantitative composition

Each 0.5 ml contains Inactivated Influenza Vaccine (Split Virion) BP as A/Sydney/5/2021 IVR-229(H1N1); A/Darwin/9/2021 SAN-010 (H3N2); B/Austria/1359417/2021 BVR-26(B-Victoria); B/Phuket/3073/2013 (B-Yamagata). Each strain contains 15 µg haemagglutinin. Viruses are propagated in SPF (Specific Pathogen Free) Chicken eggs.

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Influvax Tetra is colorless or slightly whitish liquid made by spliting and inactivating influenza virus cultured by inoculating in the allantoic cavity of embryonated eggs in order to maintain antigenic activity. Influenza virus antigen is inactivated with formaldehyde and this vaccine complies with the WHO recommendation.

4. Clinical particulars

4.1 Therapeutic indications

Influvax Tetra is recommended for adults and children from six months and above, especially those having high risk of associated complications, such as children, senior citizens, those who are susceptible and those who are in influenza epidemic areas.

The vaccine can induce body to generate immunoreaction against influenza virus and can be used for the prevention of infection caused by influenza virus.

4.2 Posology and method of administration

4.2.1 Posology

Annual influenza vaccination is recommended for persons 6 months of age and older. An intramuscular injection of the following dose and immunization of one dose is necessary in every year with same volume.

Age 6 months and older: single dose of 0.5 mL.

4.2.2 Paediatric Population

Some children will need 2 doses of influenza vaccine in the same season, administered at least 4 weeks apart. Children 6 months through 8 years of age who have never received seasonal influenza vaccine or for whom vaccination history is unknown.

4.2.3 Method of administration

Administration: Intramuscular injection (IM) on deltoid.

Influvax Tetra should be administered before the beginning of the influenza season or as required by the epidemiological situation. Vaccination should be repeated every year with an age-appropriate dose of vaccine of updated antigen composition.

4.3 Contraindications

Vaccination is prohibited when subject is diagnosed as one of the following cases.

- Febrile patient or person with malnutrition
- Patients with acute respiratory disease or other active infectious disease
- Patients in latent and convalescence period
- Person who showed anaphylaxis by the components of the product
- Person with hypersensitivity to egg, chicken, any other chicken component, and the product component
- Person who showed Guilan-Bare syndrome within 1 year from the previous influenza vaccination or person with neurological disorders
- Person diagnosed with immunodeficiency disease
- Person in inappropriate condition to be vaccinated

However, if there is a possibility of influenza infection and it is determined that there is no concern for significant disorder due to vaccination, subject may be vaccinated.

4.4 Special warnings and precautions for use

- Before use check this product visually for particles or discoloration. If either is present, do not use.
- 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.
- Intravenous administration is prohibited
- It should be used cautiously for patient with hypersensitivity history.
- The tip of needle should not penetrate blood vessel.
- Do not mix with other vaccines in same syringe.
- Pre-filled syringes are disposable and should not be reused.

- Symptoms of high fever, convulsion appear after vaccination, they should consult physicians quickly.
- Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.
- Influenza vaccine should be administered with current-year recommended strains.
- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.
- Application of immunosuppressors may decrease or inhibit immunization reactions. Person who is administrated immunoglobulin should be vaccinated the vaccine 1 month later.

4.5 Interaction with other medical products and forms of interaction

There is no data or study on co-administration of this product with other vaccines. The immunological response may be diminished if the patient is undergoing immunosuppressant treatment. Following influenza vaccination, false positive results in serologic tests using the ELISA method to detect antibodies against HIV-1, Hepatitis C, and especially HTLV-1 have been observed (The Wester Blot technique disproves the false-positive ELISA test results). These transient false-positive results could be due to the IgM response by the vaccine.

4.6 Fertility, pregnancy and lactation

4.6.1 Pregnancy

Inactivated Influenza vaccine (egg-derived) is known that it can be used in all pregnancy cycles regardless of the pregnancy stage. There are more safety data for second trimester and third trimester compared with the first trimester. In addition, according to data on the usage of inactivated influenza vaccine collected globally, no adverse effects of the vaccine on the fetus and maternity were reported. In addition, no direct or indirect adverse effects related to reproductive toxicity and developmental toxicity were observed in animal studies conducted using this vaccine. However, clinical trials have not evaluated the safety of the pregnant women when administered this vaccine.

4.6.2 Breast-feeding

Inactivated Influenza vaccine (egg-derived) is known that it can be used to lactating women. Restricted data indicate that the vaccine is not known whether the product is excreted in human milk. However, there is no adequate study of vaccination in animals during lactation, and clinical trials have not evaluated the safety of nursing mothers when administered this vaccine.

4.6.3 Fertility

No fertility data are available

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use machines have been performed. However, some of the effects mentioned under section 4.8 “Undesirable effects” may temporarily affect the ability to drive or use machines

4.8 Undesirable effects

As with all medicinal products, this product may cause undesirable effects.
• There is possibility of local reactions such as redness, swelling and pain, or systemic reactions such as fever, chills, headache, fatigue and vomiting. However, they usually disappear within 2-3 days.
• In rare cases, acute disseminated 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.
• Allergic reaction or anaphylactic shock may occur in very rare cases.
• Transient disorders of systemic and local nervous system may rarely occur. Palsy, neuralgia, cerebral hemorrhage or inflammation of the nervous system (ex: Guillain-Barre syndrome) have been reported.

4.9 Overdose

Not applicable

5. Pharmacological properties

5.1 Pharmacodynamic properties

Vaccines, Influenza vaccines

Mechanism of action

Influvax Tetra provides active immunization against four influenza virus strains (two A subtypes and two B types) contained in the vaccine. Influvax Tetra induces humoral antibodies against the haemagglutinins within 2 to 3 weeks. These antibodies neutralize influenza viruses.

Specific levels of haemagglutination-inhibition (HAI) antibody titre post-vaccination with inactivated influenza virus vaccines have not been correlated with protection from influenza illness but the HAI antibody titres have been used as a measure of vaccine activity. In some human challenge studies, HAI antibody titres of ≥1:40 have been associated with protection from influenza illness in up to 50% of subjects.

5.2 Pharmacokinetic properties

Not applicable to vaccine products.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Chloride
Potassium chloride
Disodium hydrogen phosphate dihydrate
Potassium dihydrogen phosphate
Water for injection

6.2 Incompatibilities

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

6.3 Shelf life

1 years

6.4 Special precautions for storage

Store at temperature between +2 °C to +8 °C. Store in the original package to protect from light. Do not freeze. Freezing destroys activity. Do not use vaccine which has been frozen.

6.5 Nature and contents of container

Each box contains 1 Pre-filled syringe of 0.5 ml Inactivated Influenza Vaccine (Split Virion) BP and 2 needles.

6.6 Special precautions for disposal and other handling

Influenza vaccine should not be given to individuals with Guillain-Barre syndrome, bleeding disorder. Natural latex rubber of plunger stopper of the syringe has been associate with allergic reactions. Immunocompromised persons may not obtain the expected immune response. As with any vaccine, immunization with influenza vaccine may not protect 100% of susceptible individuals.

7. Marketing authorization holder

Incepta Pharmaceuticals Limited
Vaccine Division
Savar, Dhaka,
Bangladesh

8. Drug authorization number(s)

363-40-069

9. Date of first authorization/Renewal of the authorization

25-Nov-2020

10. Date of revision of the text

24-Nov-2025