

INFORMATION FOR HEALTH PROFESSIONALS

Data Sheet

Influvac®

Inactivated influenza vaccine (surface antigen)

Composition

Active:

Inactivated influenza vaccine (surface antigen)

Inactive:

Potassium chloride, potassium dihydrogen phosphate, sodium phosphate-dibasic dihydrate, sodium chloride, calcium chloride, magnesium chloride and water for injections.

Description

Influvac is a clear colorless suspension for injection. It is an egg-grown, inactivated influenza virus vaccine based on isolated surface antigens of A and B strains of myxovirus influenza).

Actions

Pharmacology

This vaccine is used for active immunization against influenza virus, types A and B, principally for the vaccination of those groups regarded as being at special risk, especially the elderly. The vaccine stimulates production of antibodies with a specific capacity against influenza. Protection is only against those strains of the virus from which the vaccine is prepared or closely related strains. Seroprotection is obtained within 2-3 weeks. The duration of post-vaccination immunity varies, but is between 6-12 months.

Indications

For the prevention of influenza caused by influenza virus, types A and B, in adults aged 18 years and older. It is recommended for annual vaccination for the following persons:

1. All people 65 years and older.
2. People under 65 years with:
 - Cardiovascular disease - ischaemic heart disease, congestive heart failure, rheumatic heart disease, congenital heart disease, cerebrovascular disease.
 - Chronic respiratory disease - Asthma if on regular preventative therapy; other chronic respiratory disease with impaired lung condition.
 - Diabetes.
 - Chronic renal disease.
 - Any cancer, excluding basal or squamous skin cancers if not invasive.
 - Other conditions - autoimmune disease, immune suppression, HIV, transplant recipients, neuromuscular and CNS diseases, haemoglobinopathies, children on long-term aspirin.

Pregnant women

Influenza vaccination is recommended for women who are beyond the first trimester of pregnancy (i.e., greater than 14 weeks gestation) during the influenza season. Influenza vaccine should be offered for pregnant women with a medical condition (as above).

Contraindications

Hypersensitivity to eggs, chicken protein, chicken feathers, previous dose of seasonal flu vaccine, or any other constituent of the vaccine. Immunisation should be postponed in patients with an acute febrile illness.

The presence of a minor illness with or without fever should not contraindicate the use of Influvac.

Precautions

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. Influvac should not be administered intravascularly. Influvac should be administered subcutaneously to subjects with thrombocytopenia or a bleeding disorder, since bleeding may occur following an intramuscular injection. Patients with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic defect, human immunodeficiency virus (HIV) infection, or other causes, may have a reduced antibody response in active immunization procedures.

Use with caution in patients known to be hypersensitive to Gentamycin antibiotic. Patients with a history of Guillain-Barre syndrome (GBS) with an onset related in time to influenza vaccination may be at increased risk of again developing GBS if given influenza vaccine.

Interactions

Influenza vaccine can impair the metabolism of warfarin, theophylline, phenytoin, phenobarbitone and carbamazepine by the hepatic P450 system. Patients taking warfarin, theophylline, phenytoin, phenobarbitone, or carbamazepine should be advised of the possibility of an interaction and told to look out for signs of elevated levels of medication.

Influvac should not be mixed with other vaccines in the same syringe.

Use in lactation

There are no known contraindications to the use of Influvac by lactating women.

Adverse reactions

Local reactions.

Very common: redness, swelling, pain.

Common: ecchymosis, induration.

Body as a whole.

Very common: headache.

Common: fever, malaise.

Uncommon: shivering, fatigue, sweating, myalgia, arthralgia.

Very rare: neuralgia, paraesthesia, convulsions, transient thrombocytopenia, allergic reactions (such as angioedema) leading to shock.

Post-marketing Experience

Very rarely cases of rash, asthenia and vasculitis with transient renal involvement have been reported.

Dosage and Administration during the campaign:

Adults and children from 36 months: 0.5 mL

Children from 6 months to 35 months: 0.25 ml

During the seasonal flu immunization campaign two doses separated by an interval of at least four weeks are recommended.

Administration

Influvac should be administered by intramuscular or deep subcutaneous injection. Influvac should not be administered intravenously.

Influvac should not be mixed with other injection fluids. Influvac should be administered subcutaneously to subjects with thrombocytopenia or a bleeding disorder, since bleeding may occur following an intramuscular injection.

Instructions for use/handling

Influvac should be allowed to reach room temperature and shaken well before use.

Overdosage

Given the nature of the product and mode of administration the probability of overdosage is negligible.

Presentation

Single-dose 0.5 mL pre-filled glass syringe.

Storage

Store between 2 and 8 degrees Celsius. Refrigerate, Do not freeze. Protect from light.