San

INFLUVAC SH
Influenza vaccine

NAME OF THE MEDICINAL PRODUCT

Influvac, suspension for injection (influenza vaccine, surface antigen, inactivated)

QUALITATIVE AND QUANTITATIVE COMPOSITION

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

- A/California/7/2009 (H1N1)pdm09-derived strain used (NYMC X-181) 15 micrograms HA **

- A/Texas/50/2012(H3N2)-derived strain used (NYMC X-223A) 15 micrograms HA **

- B/Massachusetts/2/2012-derived strain used (NYMC BX-51B)
15 micrograms HA **

per 0.5 ml dose.
* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin.

This vaccine complies with the WHO recommendation (southern hemisphere) for the 2014 season.

For a full list of excipients see section List of excipients.

Influvac may contain traces of eggs (such as ovalbumin, chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80, or gentamicin, which are used during the manufacturing process (see section Contraindications).

PHARMACEUTICAL FORM

Suspension for injection in prefilled syringes, a colourless clear liquid, filled in single-dose syringes (glass, type I).

CLINICAL PARTICULARS

Therapeutic indications

Prophylaxis of influenza in adults over 18 years of age; especially those who run an increased risk of associated complications.

The use of Influvac should be based on official recommendations.

Posology and method of administration

Posology
Adults: 0.5 ml.

Method of Administration
Immunisation should be carried out by intramuscular or deep subcutaneous injection.

Precautions to be taken before handling or administrating the medicinal product:
For instructions for preparation of the medicinal product before administration, see section Special precautions for disposal and other handling.

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

Contraindications

Hypersensitivity to the active substances, to any of the excipients or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80, or gentamicin.

Immunisation shall be postponed in patients/children with febrile illness or acute infection.

Special warnings and precautions for use

Infections with other agents causing flu-like symptoms are not prevented by the vaccine.

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

Influvac should under no circumstances be administered intravascularly.

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

Interference with serological testing: see section Interaction with other medicinal products and other forms of interaction.

Interaction with other medicinal products and other forms of interaction

Influvac may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.

The immunological response may be diminished if the patient/child is undergoing immunosuppressant treatment.

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA test results. The transient false-positive reactions could be due to the IgM response by the vaccine.

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

Breastfeeding
Influvac may be used during breastfeeding.

Fertility
No fertility data are available

Effects on ability to drive and use machines

Influvac has no or negligible influence on the ability to drive and use machines.

Undesirable effects

ADVERSE REACTIONS OBSERVED FROM CLINICAL TRIALS
The safety of trivalent inactivated influenza vaccines is assessed in open label, uncontrolled clinical trials performed as annual update requirement, including at least 50 adults aged 18 - 60 years of age and at least 50 elderly aged 61 years or older. Safety evaluation is performed during the first 3 days following vaccination.

The following undesirable effects have been observed during clinical trials with the following frequencies:
very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1000, <1/100);
Tabulated list of adverse reactions:

Organ Class	Very common	Common ≥1/100,	Uncommon

	≥1/10	<1/10	≥1/1,000, <1/100
Nervous system disorders		Headache*	
Skin and subcutaneous tissue disorders		Sweating*	
Musculoskeletal and connective tissue disorders		Myalgia, arthralgia*	
General disorders and administration site conditions		Fever, malaise, shivering, fatigue Local reactions: redness, swelling, pain, ecchymosis induration*	

* These reactions usually disappear within 1 – 2 days without treatment

ADVERSE REACTIONS REPORTED FROM POST-MARKETING SURVEILLANCE
Adverse reactions reported from post marketing surveillance are, next to the reactions which have also been observed during the clinical trials, the following:

Blood and lymphatic system disorders:
Transient thrombocytopenia, transient lymphadenopathy

Immune system disorders:
Allergic reactions, in rare cases leading to shock, angioedema

Nervous system disorders:
Neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome.
Vascular disorders:
Vasculitis associated in very rare cases with transient renal involvement

Skin and subcutaneous tissue disorders:
Generalised skin reactions including pruritus, urticaria or non-specific rash

Overdose

Overdosage is unlikely to have any untoward effect.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC Code: J07BB02.

Influvac induces humoral antibodies against the haemagglutinins. These antibodies neutralize influenza viruses. A haemagglutinin inhibition titre equal to or greater than 1:40 in the serum is considered to be protective.

Seroprotection is generally obtained within 2 to 3 weeks. The duration of postvaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6-12 months.

Pharmacokinetic properties

Not applicable.

Preclinical safety data

Not applicable.

PHARMACEUTICAL PARTICULARS

List of excipients

Potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, sodium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate and water for injections.

Incompatibilities

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

Shelf life

1 year

Special precautions for storage

Store in a refrigerator (+2°C to +8°C).
Do not freeze.
Store in the original package in order to protect from light.

Nature and contents of container

Influvac:
0.5 ml suspension for injection in prefilled syringe with needle (glass, type I), pack of 1.
Reg No.:...

Special precautions for disposal and other handling

The vaccine should be allowed to reach room temperature before use.
Shake before use. Inspect visually prior to administration.

Influvac:
For the administration of a 0.25 ml dose from a single dose 0.5 ml syringe, push the front side of the plunger exactly to the edge of the hub (the knurled polypropylene ring); a reproducible volume of vaccine remains in the syringe, suitable for administration. See also section Posology and method of administration.

Any unused product or waste material should be disposed of in accordance with local requirements.

HARUS DENGAN RESEP DOKTER
ON MEDICAL PRESCRIPTION ONLY

Manufactured by:
Abbott Biologicals B.V.,
Veerweg 12, 8121 AA Olst, The Netherlands

Imported by:
PT Abbott Indonesia,
Jl. Raya Jakarta Bogor Km. 37, Depok, Indonesia