Influvac® 2020/2021

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

- A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like strain (A/Guangdong-Maonan/SWL1536/2019, CNIC-1909)	15 micrograms HA **
-A/Hong Kong/2671/2019 (H3N2)-like strain (A/Hong Kong/2671/2019, IVR-208)	15 micrograms HA **
-B/Washington/02/2019-like strain (B/Washington/02/2019, wild type)	15 micrograms HA **

per 0.5 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin

This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and EU recommendation for the 2020/2021 season.

For a full list of excipients see section 6.1.

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 4.3).

3. PHARMACEUTICAL FORM

Suspension for injection in prefilled syringes;
A colourless clear liquid, filled in single-dose syringes.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Prophylaxis of influenza, especially those who run an increased risk of associated complications.

Influvac is indicated in adults and children from 6 months of age.
The use of Influvac should be based on official recommendations.

4.2. Posology and method of administration

Posology
Adults: 0.5 ml.

Paediatric population

Children from 36 months onwards: 0.5 ml.

Children from 6 months to 35 months: Clinical data are limited. Dosages of 0.25 ml or 0.5 ml may be given, for detailed instructions on administering a 0.25 ml or 0.5 ml dose, see section 6.6. The dose given should be in accordance with existing national recommendations.
For children who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

Children less than 6 months: the safety and efficacy of Influvac in children less than 6 months have not been established. No data are available.

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 6.6.

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, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin.

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

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 event following the administration of the vaccine.

Influvac should under no circumstances be administered intravascularly.

As with other vaccines administered intramuscularly, Influvac should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to these subjects.

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Influvac is not effective against all possible strains of influenza virus. Influvac is intended to provide protection against those strains of virus from which the vaccine is prepared and to closely related strains.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

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

Interference with serological testing: see section 4.5.

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium- free’.

This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially “potassium- free”.

4.5. 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 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.

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

Breast-feeding
Influvac may be used during breast-feeding.

Fertility
No fertility data are available

4.7. Effects on ability to drive and use machines

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

4.8. Undesirable effects

a. Summary of safety profile

The most frequently reported adverse drug reactions following use of Influvac are local and/or systemic reactions such as injection site pain or fatigue and headache. Most of these adverse reactions are of mild to moderate intensity.
These reactions usually disappear within 1-2 days without treatment.

In rare cases, allergic reactions may evolve to shock, angioedema (see section 4.4).

b. Tabulated summary of adverse reactions

The following undesirable effects have been observed during clinical trials or are resulting from post-marketing experience with the following frequencies:
very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); and not known (adverse reactions from post-marketing experience; cannot be estimated from the available data).

Adverse Reactions Reported with Influvac				
MedDRA System Organ Class	**Very common ≥ 1/10**	**Common ≥ 1/100 to < 1/10**	**Uncommon ≥ 1/1,000 to < 1/100**	**Not Known[a] (cannot be estimated from the available data)**
Blood and lymphatic system				Transient thrombocytopenia, transient lymphadenopathy
Immune system disorders				Allergic reactions, in rare cases leading to shock, angioedema
Nervous system disorders		Headache[b]		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		Sweating[b]		Generalised skin reactions including pruritus, urticaria or non-specific rash
Musculoskeletal and connective tissue disorders		Myalgia, arthralgia[b]		
General disorders and administration site conditions		Fever, malaise, shivering, fatigue Local reactions: redness, swelling, pain, ecchymosis, induration[b]		

[a] Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure

[b] These reactions usually disappeared spontaneously within 1-2 days without treatment.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.9. Overdose

Overdosage is unlikely to have any untoward effect.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC Code: J07BB02.

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.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

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

6.3 Shelf-life

The expiry date of the product is indicated on the packaging materials

6.4 Special precautions for storage

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

6.5 Nature and contents of the container

0.5 ml suspension for injection in prefilled syringe with / without needle (glass, type I), pack of 1 or 10.
Not all pack sizes may be marketed.

6.6 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.

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 mark so that half of the volume is eliminated; a volume of 0.25 ml of the vaccine remains in the syringe, suitable for administration. See also section 4.2.

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

7 . MANUFACTURER

Abbott Biologicals B.V.
Veerweg 12
Olst
The Netherlands

8. LICENSE HOLDER

Abbott Medical Laboratories Ltd.,
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9. REGISTRATION NUMBER

033-66-22645-00

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