Influvac 2026/2027 SEASON

1. NAME OF THE MEDICINAL PRODUCT

Influvac, suspension for injection in pre-filled syringe 0.5 ml
Influenza vaccine (surface antigen, inactivated).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

- A/Missouri/11/2025 (H1N1)pdm09-like strain (A/Missouri/11/2025, IVR-279)	15 micrograms HA **
- A/Darwin/1454/2025 (H3N2)-like strain (A/Michigan/105/2025, SAN-049A)	15 micrograms HA **
- B/Tokyo/EIS13-175/2025-like strain (B/Tokyo/EIS13-175/2025, 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 2026/2027 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).

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3. PHARMACEUTICAL FORM

Suspension for injection in prefilled syringe.
A colourless clear liquid.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Influvac is indicated for active immunization for the prevention of influenza disease 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 6 months to 17 years of age: 0.5 ml.

Children less than 9 years of age, who have not previously been vaccinated with a seasonal influenza vaccine, a second dose of 0.5 ml should be given after an interval of at least 4 weeks.

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

Method of Administration
Immunisation should be carried out by intramuscular or deep subcutaneous injection.
The preferred sites for intramuscular injection are the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in children 6 months through 35 months of age, or the deltoid muscle in children from 36 months of age and adults.

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.

4.4. Special warnings and precautions for use

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

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.

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

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. Interactions with other medicinal products and other forms of interaction

No interaction studies have been performed. If Influvac is 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.

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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. 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 human 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

Data for quadrivalent Influvac Tetra are relevant to trivalent Influvac because both vaccines are manufactured using the same process and have overlapping compositions.

a. Summary of safety profile

Safety data regarding use of Influvac are based on data from (3) clinical studies using trivalent Influvac or the quadrivalent Influvac Tetra.
In two clinical studies, healthy adults 18 years of age and older, and healthy children 3 to 17 years of age were administered with quadrivalent influenza vaccine Influvac Tetra or trivalent Influvac. In a third study, the safety was assessed in healthy children from 6 months to 35 months of age administered quadrivalent influenza vaccine Influvac Tetra or a non-influenza vaccine control.

In both children studies, children from 6 months to 8 years of age received one or two doses depending on their influenza vaccination history.

Most reactions usually occurred within the first 3 days following vaccination and resolved spontaneously within 1 to 3 days after onset. The intensity of these reactions was generally mild.

In all age groups, the most frequently reported local adverse reaction was vaccination site pain.

The most frequently reported systemic adverse reactions in adults and children from 6 to 17 years of age were fatigue and headache, and for children from 3 to 5 years of age drowsiness, irritability and loss of appetite.

The most frequently reported systemic adverse reactions in children from 6 months to 35 months of age were irritability/fussiness.

In addition, overall data from clinical trials and post-marketing experience have demonstrated that the safety and tolerability profile for QIV and TIV is comparable.

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b. Tabulated summary of adverse reactions

The following undesirable effects have been observed during clinical trials or are resulting from post-marketing experience with Influvac and/or the quadrivalent influenza vaccine Influvac Tetra 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 (adults, elderly and paediatric population)				
MedDRA System Organ Class	Adults and elderly	Children		
	18 years and older	6 to 35 months	3 to 5 years	6 to 17 years
Blood and lymphatic system				
-Transient thrombocytopenia, transient lymphadenopathy	Not known[a]	Not known[a]	Not known[a]	Not known[a]
Immune system disorders				
-Allergic reactions, in rare cases leading to shock, angioedema	Not known[a]	Not known[a]	Not known[a]	Not known[a]
Nervous system disorders				
-Headache -Drowsiness -Neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome	Very common[b] - Not known[a]	- Very common Not known[a]	- Very common Not known[a]	Very common - Not known[a]
Vascular disorders				
-Vasculitis associated in very rare cases with transient renal involvement	Not known[a]	Not known[a]	Not known[a]	Not known[a]
Skin and subcutaneous tissue disorders				
-Sweating -Generalised skin reactions including pruritus, urticaria or non-specific rash	Common Not known[a]	Very common Not known[a]	Common Not known[a]	Common Not known[a]
Metabolism and nutrition disorders				
-Appetite loss	-	Very common	Very common	-
Gastrointestinal disorders				
-Nausea -Abdominal pain -Diarrhoea -Vomiting	- - - -	- - Very common Very common	- - Common Common	Very common Very common Very common Very common
Psychiatric disorders				
-Irritability/fussiness	-	Very common	Very common	-
Musculoskeletal and connective tissue disorders				
-Myalgia -Arthralgia	Common Common	- -	- -	Very common Common

Adverse Reactions Reported (adults, elderly and paediatric population)				
MedDRA System Organ Class	Adults and elderly	Children		
	18 years and older	6 to 35 months	3 to 5 years	6 to 17 years
General disorders and administration site conditions				
-Fatigue	Very common	-	-	Very common
-Fever	Uncommon	Very common	Common	Common
-Malaise	Common	-	-	Very common
-Shivering	Common	-	-	Common
Local reactions:				
-pain	Very common	Very common	Very common	Very common
-redness	Common	Very common	Very common	Very common
-swelling	Common	Common	Very common	Very common
induration	Common	Common	Very common	Very common
-ecchymosis	Common	Common	Common	Common

[a] Not known (cannot be established from available data): 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] Reported as common in elderly (≥ 61 years of age)

To report any side effect(s):

Egypt: General Administration for Pharmaceutical Vigilance

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451

Telephone: (+2)02 25354100, Extension: 1470

Fax: +202 – 23610497

Email for reporting: pv.followup@edaegypt.gov.eg

Website for reporting: https://vigiflow-eforms.who-umc.org/eg/med

Hotline: 15301

QR code:

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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.

Mechanism of action:
Influvac provides active immunisation against the influenza virus strains contained in the vaccine. Influvac induces humoral antibodies against the haemagglutinins. These antibodies neutralise influenza viruses.

Specific levels of haemagglutination inhibition (HI) antibody titres post-vaccination with inactivated influenza vaccine have not been correlated with protection from influenza virus, but the HI antibody titres have been used to determine the activity of the vaccine.

An immune response 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.

Pharmacodynamic effects

Data for Influvac Tetra are relevant to Influvac because both vaccines are manufactured using the same process and have overlapping compositions.

The efficacy of Influvac Tetra was evaluated in a randomized, observer-blind, non-influenza vaccine-controlled study (INFQ3003) conducted during 3 influenza seasons 2017 to 2019 in Europe and Asia. Healthy subjects aged 6 - 35 months received two doses of Influvac Tetra (N=1005) or non-influenza control vaccine (N=995) approximately 28 days apart. The efficacy of Influvac Tetra was assessed for the prevention of reverse transcription polymerase chain reaction (RT-PCR)-confirmed influenza A and/or B disease due to any influenza strain. All RT-PCR-positive specimens were further tested for viability in cell culture and to determine whether the circulating viral strains matched those in the vaccine.

Table: Efficacy in children 6 – 35 months of age

	Influvac Tetra N=1005	Non-influenza control-vaccine N=995	Vaccine efficacy (95% CI)
Laboratory-confirmed influenza caused by:	n	n	
- **Any influenza A or B strain**	59	117	0.54 (0.37 - 0.66)
- **Culture confirmed vaccine matching strains**	19	56	0.68 (0.45, 0.81)

Vaccine efficacy: proportion of influenza cases prevented by the vaccination
N=number of subjects vaccinated
n=number of influenza cases
CI=confidence interval

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Immunogenicity of Influvac:

Clinical studies performed in adults of 18 years of age and older (INFQ3001) and children of 3 to 17 years of age (INFQ3002) assessed the safety and immunogenicity of Influvac Tetra and its non-inferiority to trivalent influenza vaccine Influvac formulations for the postvaccination HI Geometric mean antibody titer (GMT) and seroconversion rates. In both studies the immune response elicited by Influvac Tetra against the three strains in common was non-inferior to trivalent influenza vaccine Influvac.

Adults 18 years of age and older:

In clinical study INFQ3001, 1535 adults of 18 years of age and older received a single dose of quadrivalent Influvac Tetra and 442 subjects received a single dose of Influvac:

Table: Post-vaccination GMT and Seroconversion rates in adults

Adults 18 – 60 years of age	Influvac Tetra N=768	Influvac[1] N=112	Influvac[2] N=110
	GMT (95% confidence interval)		
A/H1N1	272.2 (248.0 , 298.8)	304.4 (235.1 , 394.1)	316.0 (245.1 , 407.3)
A/H3N2	442.4 (407.6 , 480.2)	536.5 (421.7 , 682.6)	417.0 (323.7 , 537.1)
B (Yamagata)[3]	162.5 (147.8 , 178.7)	128.7 (100.3 , 165.2)	81.7 (60.7 , 109.9)

B (Victoria)[4]	214.0 (195.5 , 234.3)	85.1 (62.6 , 115.6)	184.7 (139.0 , 245.3)
Seroconversion Rates (95% confidence interval)			
A/H1N1	59.4% (55.8% , 62.9%)	65.5% (55.8% , 74.3%)	64.8% (55.0% , 73.8%)
A/H3N2	51.3% (47.7% , 54.9%)	61.6% (51.9% , 70.6%)	55.5% (45.7% , 64.9%)
B (Yamagata)[3]	59.2% (55.7% , 62.8%)	58.7% (48.9% , 68.1%)	40.9% (31.6% , 50.7%)
B (Victoria)[4]	70.2% (66.8% , 73.4%)	51.4% (41.6% , 61.1%)	66.4% (56.7% , 75.1%)

Elderly 61 years of age and older	Influvac Tetra N=765	Influvac[1] N=108	Influvac[2] N=110
	GMT (95% confidence interval)		
A/H1N1	127.2 (114.9 , 140.9)	142.4 (107.6 , 188.3)	174.2 (135.9 , 223.3)
A/H3N2	348.5 (316.8 , 383.5)	361.5 (278.3 , 469.6)	353.4 (280.7 , 445.0)
B (Yamagata)[3]	63.7 (57.7 , 70.4)	57.4 (43.6 , 75.7)	27.3 (20.7 , 36.0)
B (Victoria)[4]	109.4 (98.1 , 122.0)	48.0 (34.6 , 66.6)	106.6 (79.7 , 142.8)
Seroconversion Rates (95% confidence interval)			
A/H1N1	50.3% (46.7% , 54.0%)	56.6% (46.6% , 66.2%)	58.2% (48.4% , 67.5%)
A/H3N2	39.3% (35.8% , 42.9%)	44.4% (34.9% , 54.3%)	43.6% (34.2% , 53.4%)
B (Yamagata)[3]	49.9% (46.2% , 53.5%)	46.2% (36.5% , 56.2%)	30.0% (21.6% , 39.5%)
B (Victoria)[4]	53.6% (50.0% , 57.2%)	25.0% (17.2% , 34.3%)	55.6% (45.7% , 65.1%)

N= number of subjects included in immunogenicity analysis

[1]containing A/H1N1, A/H3N2 and B (Yamagata lineage)
[2]containing A/H1N1, A/H3N2 and B (Victoria lineage)
[3]recommended B strain by WHO for the season 2014-2015 NH for trivalent vaccines
[4]additional recommended B strain by WHO for season 2014-2015 NH for quadrivalent vaccines

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Paediatric population

Children 3 - 17 years of age:

In clinical study INFQ3002, 402 children of 3 to 17 years of age received one or two doses of quadrivalent Influvac Tetra and 798 children received one or two doses of Influvac based on their influenza vaccination history.

Table: Seroconversion rates in children 3 -17 years of age

Children 3 - 17 years of age	Influvac Tetra N=396	Influvac[1] N=389	Influvac[2] N=399
Seroconversion Rates (95% confidence interval)			
A/H1N1	60.1% (55.1% , 65.0%)	61.8% (56.7% , 66.6%)	59.1% (54.1% , 64.0%)
A/H3N2	80.6% (76.3% , 84.3%)	82.4% (78.3% , 86.1%)	80.7% (76.5% , 84.5%)
B (Yamagata)[3]	79.3% (75.0% , 83.2%)	73.1% (68.4% , 77.5%)	28.1% (23.7% , 32.8%)
B (Victoria)[4]	76.5% (72.0% , 80.6%)	39.5% (34.6% , 44.6%)	72.7% (68.0% , 77.0%)

N= number of subjects included in immunogenicity analysis

[1]containing A/H1N1, A/H3N2 and B (Yamagata lineage)
[2]containing A/H1N1, A/H3N2 and B (Victoria lineage)
[3]recommended B strain by WHO for the season 2016-2017 NH for trivalent vaccines
[4]additional recommended B strain by WHO for season 2016-2017 NH for quadrivalent vaccines

Children 6 months - 35 months of age:

In clinical study INFQ3003 the immunogenicity of Influvac Tetra was evaluated in terms of seroconversion rates across 3 influenza seasons.

Table: Seroconversion rates in children 6 – 35 months of age

Children 6 - 35 months of	Influenza season	Influenza season NH 2018-2019[1]	Influenza season SH 2019[1]

age	NH 2017-2018[1] N=348		N=359		N=225	
	Seroconversion Rates (95% confidence interval)					
A/H1N1	74.4%	(69.5% , 78.9%)	76.0%	(71.3% , 80.4%)	69.8%	(63.3% , 75.7%)
A/H3N2	92.5%	(89.2% , 95.0%)	86.6%	(82.7% , 90.0%)	86.2%	(81.0% , 90.4%)
B (Yamagata)	35.5%	(30.4% , 40.8%)	56.0%	(50.7% , 61.2%)	16.9%	(12.2% , 22.4%)
B (Victoria)	26.5%	(21.9% , 31.5%)	65.2%	(60.0% , 70.1%)	47.6%	(40.9% , 54.3%)

N= number of subjects included in immunogenicity analysis
[1]containing recommended strains by WHO for respective season for quadrivalent vaccines

5.2 Pharmacokinetic properties

Not applicable.

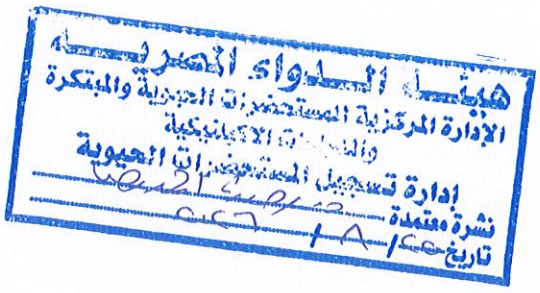
5.3 Preclinical safety data

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Potassium chloride
- Potassium dihydrogen phosphate
- Disodium phosphate dihydrate
- Sodium chloride
- Calcium chloride dihydrate
- Magnesium chloride hexahydrate
- 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

1 year.

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 or without needle (glass, type I), with plunger stopper (bromobutyl rubber), pack of 1 or 10.
Not all packs sizes may be marketed.

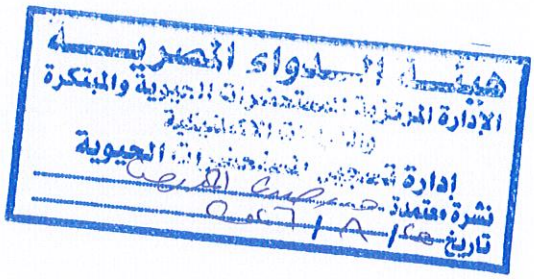
6.6 Special precautions for disposal and other handling

The vaccine should be allowed to reach room temperature before use.
Shake before use. Inspect visually prior to administration.
Do not use the vaccine if the colour has changed or foreign particles are present in the suspension.

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

7. MARKETING AUTHORISATION HOLDER

Abbott Biologicals B.V.
C.J. van Houtenlaan 36
1381 CP Weesp
The Netherlands
tel: (0294) 477000



Manufacturer:
Abbott Biologicals B.V.
Veerweg 12 NL-8121 AA Olst The Netherlands

8. Date Of First Autharization

May 2025

9. DATE OF REVISION OF THIS TEXT

June 2026
This summary of product characteristics is approved by the Egyptian Drug Authority.