Influvac Suspension for Injection

2026/2027NH

Package Insert

INFLUVAC® 2026/2027

1. 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 competent authority decision for the 2026/2027 season. For a full list of excipients see section 5.1.

Influvac® 2026/2027 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 3.3).

2. PHARMACEUTICAL FORM

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

3. CLINICAL PARTICULARS

3.1. Therapeutic indications

Influvac® is indicated for active immunisation 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.

3.2. 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 5.6.

3.3. Contraindications

Hypersensitivity to the active substances, to any of the excipients listed in section 5.1 or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin.

3.4. 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® 2026/2027 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 3.5.

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”.

3.5. Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. If Influvac® 2026/2027 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.

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.

3.6. 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.

Breastfeeding

Influvac® 2026/2027 may be used during breastfeeding.

Fertility

No human fertility data are available.

3.7. Effects on ability to drive and use machines

Influvac® 2026/2027 has no or negligible influence on the ability to drive and use machines.

3.8. 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.

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
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)

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

3.9 Overdose

Overdosage is unlikely to have any untoward effect.

4. PHARMACOLOGICAL PROPERTIES

4.1. 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 post vaccinal 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 trivalent Influvac® because both vaccines are manufactured using the same process and have overlapping compositions.

Efficacy of Influvac® Tetra in children 6 - 35 months of age:

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

Immunogenicity of trivalent 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® 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, 1,535 adults of 18 years of age and older received a single dose of Influvac® Tetra and 442 subjects received a single dose of trivalent 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

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 Influvac® Tetra and 798 children received one or two doses of trivalent 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 immunogenocity 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 age	Influenza season NH 2017-2018[1] N=348	Influenza season NH 2018-2019[1] N=359	Influenza season SH 2019[1] 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

4.2. Pharmacokinetic properties

Not applicable.

4.3. 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.

5. PHARMACEUTICAL PARTICULARS

5.1. List of excipients

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

5.2. Incompatibilities

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

5.3. Shelf-life

1 year.

5.4. 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.

5.5. 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 pack sizes may be marketed.

5.6. 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.

6. MANUFACTURER

Abbott Biologicals B.V.
Veerweg 128121
AA Olst
The Netherlands

7. DATE OF APPROVAL/REVISION OF THIS TEXT

Sep 2026

RDCCDS000650/4

Influvac Suspension for Injection

2026 SH

Package Insert

INFLUVAC 2026

1. 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/Switzerland/6849/2025, IVR-278)	15	micrograms	HA**
- A/Singapore/GP20238/2024 (H3N2)-like strain (A/Singapore/GP20238/2024, IVR-277)	15	micrograms	HA**
- B/Austria/1359417/2021-like strain (B/Austria/1359417/2021, BVR-26)	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 (southern hemisphere) and competent authority decision for the 2026 season. For a full list of excipients see section 5.1.

Influvac® 2026 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 3.3).

2. PHARMACEUTICAL FORM

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

3. CLINICAL PARTICULARS

3.1. 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.

Vaccination is particularly recommended for the following categories of patients, depending on national immunization policies:

- Persons aged ≥ 65 years, regardless their health condition.
- Adults and children with chronic disorders of the pulmonary or cardiovascular systems, including asthma.
- Adults and children with chronic metabolic diseases such as diabetes mellitus.
- Adults and children with chronic renal dysfunction.
- Adults and children with immunodeficiencies due to disease or immunosuppressant medication (e.g., cytostatics or corticosteroids) or radiotherapy.
- Children and teenagers (6 months – 18 years) who receive long-term acetylsalicylic acid containing medication and might therefore be at risk for developing Reye's syndrome following an influenza infection.

3.2. 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 5.6. 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 5.6.

3.3. Contraindications

Hypersensitivity to the active substances, to any of the excipients listed in section 5.1 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.

3.4. 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® 2026 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 vaccines. Antibody response in patients with endogenous or iatrogenic immunosuppression maybe insufficient. Interference with serological testing: see section 3.5.

This medicine contains less than 1mmol 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".

3.5. Interaction with other medicinal products and other forms of interaction

Influvac® 2026 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.

3.6. 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. Breastfeeding Influvac® 2026 may be used during breastfeeding. Fertility No fertility data are available

3.7. Effects on ability to drive and use machines

Influvac® 2026 has no or negligible influence on the ability to drive and use machines.

3.8. 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 3.4)

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, <1/10**	**Uncommon 1/1,000, <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, paraethesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barre 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, in duration[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 disappear within 1-2 days without treatment.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

3.9. Overdose

Overdosage is unlikely to have any untoward effect.

4. PHARMACOLOGICAL PROPERTIES

4.1. Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC Code: J07BB02.

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

4.2. Pharmacokinetic properties

Not applicable.

4.3. Preclinical safety data

Not applicable.

5. PHARMACEUTICAL PARTICULARS

5.1. List of excipients

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

5.2. Incompatibilities

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

5.3. Shelf-life

1 year.

5.4. 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.

5.5. Nature and contents of the container

0.5 ml suspension for injection in prefilled syringe with or without needle (glass, type I) pack of 1 or 10.

5.6. 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 3.2.

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

6. MANUFACTURER

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7. DATE OF APPROVAL/REVISION OF THIS TEXT

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