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 (inactivated) (haemagglutinin and neuraminidase) of the following strains*:
-A/Missouri/11/2025 (H1N1)pdm09-like virus
(A/Switzerland/6849/2025, IVR-278)
15
micrograms HA **

-A/Singapore/GP20238/2024(H3N2)-like virus
(A/Singapore/GP20238/2024, IVR-277)

15 micrograms HA **
-B/Austria/1359417/2021-like virus
(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 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.

CLINICAL PARTICULARS
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.

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 Special precautions for disposal and other handling. Those 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
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
Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administrated 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/children 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 stressrelated 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/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.

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".

Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed. If 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 human 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
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

Safey 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 systematic adverse reactions in adults and children from 6 to 17 years of age were fatigues and headache, and for children from 3 to 5 years of age drowsiness, irritability and loss of appetite.

The most frequently reported systematic 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 or 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 Reaction 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				
- Trancient thrombocytopenia, transient lymphadenopathy	Not known[a]	Not known[a]	Not known[a]	Not known[a]
Immune system disorders				
- Allergic reaction, 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 colvulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barre 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 reaction including pruritus, urticaria on 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 -Fever -Malaise -Shivering Local reactions: -Pain -Redness -Swelling -Induration -Ecchymosis	Very common Uncommon Common Common Very common Common Common Common Common	- Very common - - Very common Very common Common Common Common	- Common - - Very common Very common Very common Very common Common	Very common Common Very common Common Very common Very common Very common Very 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 casual 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 email: pv.indonesia@abbott.com and/or via:

Pusat MESO/Farmakovigilans Nasional
Direktorat Pengawasan Distribusi Produk Terapetik dan PKRT Badan POM RI
Jl. Percetakan Negara 23 Jakarta Pusat, 10560
No. Telp: 021-4244 755 ext.111
Fax: 021-4288 3485
Email: pv-center@pom.go.id dan Indonesia-MESO-BadanPOM@hotmail.com

OVERDOSE
Overdosage is unlikely to have any untoward effect.

PHARMACOLOGIC PROPERTIES
Pharmacodynamic Properties
Pharmacotherapeutic group: Influenza vaccine, ATC Code: J07BB02.

Mechanism of Action
Influvac provides active immunization against the influenza virus strains contained in the vaccine. Influvac induces humoral antibodies against the haemagglutinins. These antibodies neutralize influenza viruses.

Specific levels of haemagglutination inhibition (HI) antibody tires 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.

Efficacy 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 Influvac:
Clinical studies performed in adults of 18 years of age and older

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(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

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 ,	304.4 (235.1 , 394.1)	316.0 (245.1 , 407.3)
A/H3N2	442.4 (407.6 ,	536.5 (421.7 , 682.6)	417.0 (323.7 , 537.1)
B (Yamagata)[3]	162.5 (147.8 ,	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%,	65.5% (55.8%,	64.8% (55.0%, 73.8%)
A/H3N2	51.3% (47.7%,	61.6% (51.9%,	55.5% (45.7%, 64.9%)
B (Yamagata)[3]	59.2% (55.7%,	58.7% (48.9%,	40.9% (31.6%, 50.7%)
B (Victoria)[4]	70.2% (66.8%,	51.4% (41.6%,	66.4% (56.7%, 75.1%)

Elderly 61 years of age	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]	306.7	(266.0 , 353.6)	104.5	(86.8 , 125.8)	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 age	Influvac® season NH 2017-2018[1] N=348		Influvac® season NH 2018-2019[1] N=359		Influvac® 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.

Pharmacokinetic Properties
Not applicable
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.

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 - 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.

Special precautions for disposal and other handling
The vaccine should be allowed to reach room 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 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 Posology and method of 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

ON MEDICAL PRESCRIPTION ONLY
HARUS DENGAN RESEP DOKTER
Reg No. : DKI1281601443A1

Manufactured by :
Abbott Biologicals B.V.,
C.J. van Houtenlaan 36, 1381CP, Weesp, Netherlands

Packed and Released by:
Abbott Biologicals B.V.
Veerweg 12, 8121 AA Olst, The Netherlands

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

Refer to CCDS v4.0/RDCCDS000650/4
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Abbott

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Informasi untuk Pasien
Influvac SH
Vaksin influenza
suspensi untuk injeksi dalam *pre-filled syringe* 0,5 ml (1 dosis)

Bacalah seluruh isi *leaflet* ini dengan cermat sebelum Anda atau anak Anda divaksin, karena leaflet ini mengandung informasi penting untuk Anda atau anak Anda.
- Simpanlah *leaflet* ini. Anda mungkin perlu membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, bertanyalah pada dokter atau apoteker Anda.
- Vaksin ini diresepkan untuk Anda atau anak Anda. Jangan diserahkan pada orang lain.
- Jika Anda atau anak Anda mengalami efek samping, komunikasikan dengan dokter atau apoteker Anda. Ini meliputi kemungkinan efek samping apa pun yang tidak tercantum di dalam *leaflet* ini. Lihat poin 4

Isi dalam *leaflet* ini

1. Apakah Influvac dan digunakan untuk apa
2. Apa yang Anda perlu ketahui sebelum Anda atau anak Anda menggunakan Influvac
3. Bagaimana menggunakan Influvac
4. Kemungkinan efek samping
5. Bagaimana menyimpan Influvac
6. Isi kemasan dan informasi lain

1. Apakah Influvac dan digunakan untuk apa
Influvac merupakan vaksin untuk dewasa dan anak-anak mulai dari umur 6 bulan keatas. Vaksin ini membantu untuk melindungi Anda atau anak Anda dari flu (influenza), khususnya pada subyek yang menghadapi risiko tinggi dari komplikasi terkait. Pemberian Influvac sebaiknya didasarkan pada rekomendasi resmi.

Ketika seseorang diberi vaksin Influvac, sistem kekebalan (sistem pertahanan alami tubuh) akan membentuk perlindungannya sendiri (antibodi) terhadap penyakit. Tidak satu pun bahan di dalam vaksin ini dapat menyebabkan flu.

Flu adalah penyakit yang dapat menyebar dengan cepat dan disebabkan oleh berbagai tipe *strain* yang dapat berubah setiap tahun. Oleh karena itu, inilah sebabnya mengapa Anda atau anak Anda mungkin perlu divaksin setiap tahun. Risiko terbesar seseorang terkena flu adalah selama musim dingin antara Oktober dan Maret. Jika Anda atau anak Anda tidak divaksin pada musim gugur, masih masuk akal untuk divaksin sampai musim semi karena Anda atau anak Anda menghadapi risiko terkena flu hingga saat itu. Dokter Anda dapat merekomendasikan waktu terbaik untuk divaksin.

Influvac akan melindungi Anda atau anak Anda dari tiga *strain* virus yang terkandung di dalam vaksin mulai dari 2 sampai 3 minggu sesudah disuntik.

Waktu antara terinfeksi flu dan munculnya penyakit (periode inkubasi) adalah beberapa hari, jadi jika Anda atau anak Anda terkena flu tepat sebelum atau setelah vaksinasi, penyakit mungkin akan tetap berkembang.

Vaksin ini tidak akan melindungi Anda dan anak Anda dari *common cold*, walaupun sebagian gejalanya serupa dengan flu.

2. Apa yang Anda perlu ketahui sebelum Anda atau anak Anda menggunakan Influvac
Untuk memastikan bahwa Influvac cocok untuk Anda atau anak Anda, adalah penting untuk memberitahu dokter atau apoteker jika salah satu dari poin di bawah ini berkaitan dengan Anda atau anak Anda. Jika ada hal apa pun yang Anda tidak mengerti, mintalah agar dokter atau apoteker Anda memberikan penjelasan.

Jangan gunakan Influvac
Jika Anda atau anak Anda alergi terhadap:
- zat aktif, atau
- salah satu dari bahan lain dalam Influvac (lihat poin 6), atau

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- komponen mana pun yang mungkin ada dalam jumlah yang sangat kecil seperti telur (*ovalbumin* (tipe tertentu protein) atau protein ayam), *formaldehyde* (gas tak berwarna dengan bau yang menyengat), *cetyltrimethylammonium bromide* (zat kimia), *polysorbate* 80 (zat seperti minyak yang dipakai di dalam produk obat dan produk gizi) atau *gentamicin* (antibiotik yang dipakai untuk mengobati infeksi bakteri).

Jika Anda atau anak Anda jatuh sakit dengan suhu badan yang tinggi atau infeksi yang parah, maka vaksinasi harus ditunda hingga setelah Anda atau anak Anda sembuh.

Peringatan dan tindak pencegahan

Anda sebaiknya memberitahu dokter Anda sebelum vaksinasi jika Anda atau anak Anda memiliki:
- gangguan system imunitas (imunodefisiensi atau mengkonsumsi obat yang mempengaruhi system imunitas)
- masalah pendarahan atau memiliki kecenderungan terjadinya memar pada kulit.

Dokter Anda akan memutuskan jika Anda atau anak Anda sebaiknya menerima vaksin.

Jika Anda atau anak Anda jatuh sakit dengan suhu badan yang tinggi atau infeksi yang parah, maka vaksinasi harus ditunda hingga setelah Anda atau anak Anda sembuh.

Pingsan, merasa lemas atau reaksi lain yang terkait dengan *stress* mungkin terjadi sesudah, atau bahkan sebelum disuntik. Oleh karena itu, beritahu dokter atau perawat Anda kalau Anda atau anak Anda pernah mengalami reaksi semacam ini akibat suntikan sebelumnya.

Jika Anda atau anak Anda menjalani tes darah dalam waktu beberapa hari setelah vaksinasi flu, harap beritahu dokter Anda. Hal ini dikarenakan adanya hasil tes darah *false-positive* yang ditemukan pada beberapa pasien yang baru mendapatkan vaksin.

Sebagaimana halnya dengan semua vaksin, vaksin ini mungkin tidak sepenuhnya melindungi semua orang yang divaksin.

Obat lain dan Influvac
- Harap beritahu dokter atau apoteker Anda kalau Anda atau anak Anda sedang, baru saja, atau mungkin mengkonsumsi, obat lain apa pun, termasuk obat yang diperoleh tanpa resep.
- Tidak ada uji klinik interaksi obat yang dilakukan untuk vaksin ini.
- Influvac boleh diberikan pada waktu yang sama dengan vaksin lain dengan cara menggunakan kaki atau lengan yang satu lagi. Harap diperhatikan bahwa pemberian bersamaan dengan vaksin lain dapat memberikan efek samping lebih kuat.
- Respon system kekebalan tubuh mungkin berkurang jika pasien sedang mendapatkan perawatan *immunosuppressant*, seperti pengobatan dengan kortikosteroid, obat-obat sitostatik, atau radioterapi.

Kehamilan dan menyusui
Jika Anda hamil atau menyusui, berpikir mungkin Anda hamil atau sedang dalam rencana untuk memiliki bayi, konsultasikan dahulu kepada dokter Anda sebelum menggunakan Influvac.

Vaksin flu dapat diberikan dalam semua tahap kehamilan. Terdapat data keamanan yang lebih besar pada kehamilan trimester kedua dan ketiga dibandingkan trimester pertama. Meskipun demikian, data penggunaan vaksin flu dari seluruh dunia tidak menunjukkan vaksin dapat menyebabkan efek yang membahayakan kehamilan atau janin.

Influvac boleh diberikan dalam masa menyusui.

Dokter/apoteker Anda akan memutuskan apakah Anda atau anak Anda sebaiknya diberikan Influvac. Mintalah petunjuk dokter atau apoteker Anda sebelum mengkonsumsi obat apa pun.

Berkendara dan mengoperasikan mesin
Vaksin ini tidak mempunyai atau hanya sedikit berpengaruh terhadap kemampuan berkendara atau

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mengoperasikan mesin.

Influvac mengandung kurang dari 1 mmol natrium (23 mg) per dosis, dapat dianggap bebas natrium.
Influvac mengandung kurang dari 1 mmol kalium (39 mg) per dosis, dapat dianggap bebas kalium.

3. Bagaimana menggunakan Influvac

Penggunaan untuk dewasa
Dewasa mendapatkan satu dosis 0,5 ml.

Penggunaan untuk anak
Anak-anak 36 bulan keatas mendapatkan satu dosis 0,5 ml.
Anak-anak 6 – 35 bulan dapat diberikan dosis 0.25 mL atau 0.5 mL sesuai dengan rekomendasi.

Cara penggunaan
Dokter Anda akan memberikan dosis yang direkomendasikan untuk vaksin ini sebagai injeksi ke dalam otot atau injeksi di bawah kulit.

Jika Anda ingin mengajukan pertanyaan apa pun lebih lanjut tentang penggunaan produk ini, tanyakan kepada dokter atau apoteker Anda.

4. Kemungkinan efek samping

Seperti semua obat, Influvac mungkin menimbulkan efek samping, walaupun tidak setiap orang mengalaminya.

Hubungi segera dokter Anda jika Anda atau anak Anda mengalami salah satu dari efek samping berikut ini – Anda atau anak Anda mungkin memerlukan perawatan medis yang mendesak:
Reaksi alergi yang parah (frekuensinya tidak diketahui, terjadi sesekali selama penggunaan lazim vaksin influenza Influvac)

- yang mungkin mengakibatkan keadaan gawat darurat medis dengan tekanan darah rendah, sesak napas, jantung berdetak kencang dan nadi lemah, kulit dingin dan lembab karena keringat, pusing, yang mungkin mengakibatkan Anda atau anak Anda kolaps (syok/kejutan).
- pembengkakan yang paling jelas terlihat di kepala dan leher, termasuk wajah, bibir, lidah, tenggorokan, atau bagian lain mana pun dari tubuh dan yang mungkin menyebabkan kesulitan ketika menelan atau bernafas (*angioedema*).

Selama percobaan klinis dengan Influvac, beberapa efek samping berikut ini telah diamati. Sesuai frekuensi kejadiannya, efek samping digolongkan menjadi:

- Sangat umum (berpengaruh terhadap lebih dari 1 dalam 10 orang)
- Umum (berpengaruh terhadap 1 dalam 10 orang)
- Tidak umum (berpengaruh terhadap 1 dalam 100 orang); dan
- Tidak diketahui (reaksi yang tidak diinginkan dari pengalaman paska pemasaran; tidak dapat di estimasi dari ketersediaan data)

Efek samping	**Dewasa dan Usia Lanjut**	**Anak-anak**		
	18 tahun keatas	**6 – 35 bulan**	**3 – 5 tahun**	**6 – 17 tahun**
Sakit kepala	Sangat umum*	-	-	Sangat umum
Mengantuk	-	Sangat umum	Sangat umum	-
Berkeringat	Umum	Sangat umum	Umum	-
Hilang nafsu makan	-	Sangat umum	Sangat umum	-
Mual	-	-	-	Sangat umum
Nyeri perut	-	-	-	Sangat umum
Diare	-	Sangat umum	Umum	Sangat umum
Muntah	-	Sangat umum	Umum	Sangat umum

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Mudah marah/rewel	-	Sangat umum	Sangat umum	-
Nyeri otot	Umum	-	-	Sangat umum
Nyeri sendi	Umum	-	-	Umum
Kelelahan	Sangat umum	-	-	Sangat Umum
Demam	Tidak umum	Sangat umum	Umum	Umum
Pada umumnya merasa tidak enak badan	Umum	-	-	Sangat umum
Menggigil	Umum	-	-	Umum
Nyeri pada bagian yang disuntik	Sangat umum	Sangat umum	Sangat umum	Sangat umum
Kemerahan	Umum	Sangat umum	Sangat umum	Sangat umum
Pembengkakan	Umum	Umum	Sangat umum	Sangat umum
Pengerasan disekitar bagian yang disuntik	Umum	Umum	Sangat umum	Sangat umum
Memar	Umum	Umum	Umum	Umum
Untuk semua usia: Tidak diketahui (tidak bisa diperkirakan dari data yang tersedia)	Reaksi kulit yang mungkin dapat menyebar keseluruh tubuh termasuk rasa gatal pada kulit, ruam kulit			
	peradangan pembuluh darah yang mungkin mengakibatkan ruam kulit, dan dalam kasus yang sangat jarang terjadi, masalah ginjal yang berlangsung sementara.			
	rasa sakit di sistem saraf (neuralgia), kelainan pada persepsi sentuhan, rasa sakit, rasa panas dan dingin (paraesthesia), kejang terkait demam gangguan saraf yang mungkin mengakibatkan leher kaku, kebingungan, mati rasa, nyeri dan kelemahan lengan dan kaki, hilangnya keseimbangan, hilangnya refleks, mati rasa sebagian atau seluruh badan (peradangan otak dan urat saraf tulang belakang, peradangan saraf, peradangan saraf dengan serangan mendadak [*Guillain-Barré Syndrome*])			
	penurunan sementara jumlah *platelet* yang dapat menyebabkan memar atau pendarahan yang berlebihan (*transient thrombocytopenia*); pembengkakan sementara kelenjar di dalam leher, ketiak, atau selangkangan (*transient lymphadenopathy*)			
*Umum pada usia lanjut (≥ 61 tahun)				

Untuk semua kelompok umur, sebagian besar reaksi biasanya terjadi dalam 3 hari pertama setelah vaksinasi, dapat hilang spontan dalam 1 hingga 3 hari setelah vaksin bekerja, intensitas reaksi ini umumnya ringan.

Pelaporan efek samping

Jika Anda atau anak Anda mengalami efek samping, hubungi dokter atau apoteker Anda. Ini termasuk kemungkinan efek samping apa pun yang tidak tercantum dalam leaflet ini. Anda juga dapat melaporkan efek samping langsung melalui email: pv.indonesia@abbott.com.

Dengan melaporkan efek samping, Anda dapat membantu dalam memberikan informasi lebih banyak tentang keamanan Influvac.

5. Bagaimana menyimpan Influvac

Jauhkan Influvac jangan sampai dilihat dan dijangkau oleh anak-anak.

Jangan menggunakan Influvac setelah tanggal habis masa berlakunya, yang tertera di kotak kardus setelah kata “EXP”. Kata “bulan” dan kata “tahun” disebutkan. Tanggal habis masa berlakunya

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mengacu pada hari terakhir bulan tersebut.

Simpan di dalam lemari pendingin (2°C - 8°C). Jangan dibekukan.

Simpan produk ini di dalam kemasannya semula untuk melindunginya dari cahaya.

Obat sebaiknya tidak dibuang ke limbah pengairan atau limbah rumah tangga. Tanyalah kepada apoteker Anda bagaimana membuang obat yang tidak lagi diperlukan. Semua tindak pencegahan ini akan membantu dalam melindungi lingkungan hidup.

6. Isi kemasan dan informasi lain

Influvac berisi apa
Beberapa zat aktif di dalam Influvac adalah:
Influenza virus surface antigens (inactivated) (haemagglutinin and neuraminidase) dalam beberapa *strain** berikut ini:

-A/Missouri/11/2025 (H1N1)pdm09-like virus (A/Switzerland/6849/2025, IVR-278)	15 micrograms HA **
-A/Singapore/GP20238/2024(H3N2)-like virus (A/Singapore/GP20238/2024, IVR-277)	15 micrograms HA **
-B/Austria/1359417/2021-like virus (B/Austria/1359417/2021, BVR-26)	15 micrograms HA **

per 0.5 ml dose.

* dikembangbiakkan di dalam telur ayam yang dibuahi dari ayam sehat
** *haemagglutinin*

Vaksin ini mematuhi rekomendasi *World Health Organisation (WHO) (souththern hemisphere)* dan rekomendasi Uni Eropa untuk **musim 2026**.

Bahan lain adalah: *potassium chloride*, *potassium dihydrogen phosphate*, *disodium phosphate dihydrate*, *sodium chloride*, *calcium chloride dihydrate*, *magnesium chloride hexahydrate*, dan *water for injection.*

Seperti apa tampilan Influvac dan isi kemasannya
Influvac merupakan suspensi untuk injeksi dalam *pre-filled syringe* 0,5 ml yang berisi 0,5 ml cairan injeksi yang bening tanpa warna. Setiap *pre-filled syringe* hanya boleh dipakai satu kali.
Dus, 1 *pre-filled syringe* @ 0,5 ml (1 dosis).

HARUS DENGAN RESEP DOKTER

Reg. No.: DKI1281601443A1

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