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Packaging & Label Management

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PRODUCT NAME: Influvac Tetra 0.5 ml Suspension for injection

AFFILIATE ORIGINATOR: Indonesia Influvac

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Abbott

1141319

INFLUVAC® TETRA NH
Influenza vaccine

1. NAME OF THE MEDICINAL PRODUCT
Influvac® Tetra, suspension for injection in pre-filled syringe 0.5 ml (single dose)
(influenza vaccine, surface antigen, inactivated).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Influenza virus surface antigens (inactivated) (haemagglutinin and neuraminidase) of the following strains*:

- A/Victoria/4897/2022(H1N1)pdm09-like virus (A/Victoria/4897/2022, IVR-238)	15 micrograms HA **
- A/Croatia/10136RV/2023 (H3N2)-like virus (A/Croatia/10136RV/2023, X-425A)	15 micrograms HA **
- B/Austria/1359417/2021-like virus (B/Austria/1359417/2021, BVR-26)	15 micrograms HA **
- B/Phuket/3073/2013-like virus (B/Phuket/3073/2013, 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 **2025/2026 season.**

For a full list of excipients see section 6.1.

Influvac® Tetra 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 pre-filled syringe;
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® Tetra is indicated in adults and children from 6 months of age.
The use of Influvac® Tetra should be based on official recommendations.

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

4.2. Posology and method of administration
Posology
Adults: 0.5 ml.

Paediatric patients
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 of age: the safety and efficacy of Influvac® Tetra have not been established.

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.

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

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 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.

Influvac® Tetra should under no circumstances be administered intravascularly.

As with other vaccines administered intramuscularly, Influvac® Tetra 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® Tetra is not effective against all possible strains of influenza virus. Influvac® Tetra 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
No interaction studies have been performed. If Influvac® Tetra 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.

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® Tetra may be used during breast-feeding.

Fertility
No fertility data are available.

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

4.8. Undesirable effects
a. Summary of the safety profile
The safety of Influvac® Tetra was assessed in three clinical trials in which healthy adults 18 years of age and older, and healthy children 3 to 17 years of age were administered Influvac® Tetra or trivalent influenza vaccine Influvac®. In a third study, the safety of Influvac® Tetra was assessed in healthy children from 6 months to 35 months of age administered Influvac® Tetra of a non-influenza vaccine control.

In both children studies, children from 6 months to 8 years of age received one or two doses of Influvac® Tetra 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 after vaccination observed in the clinical studies for Influvac® Tetra was vaccination site pain.
The most frequently reported general adverse reactions after vaccination observed in the clinical studies for Influvac® Tetra 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 general adverse reactions after vaccination observed in the clinical studies for Influvac® Tetra in children from 6 months to 35 months of age were irritability/fussiness.

Similar rates of solicited adverse reactions were observed in recipients of Influvac® Tetra and trivalent influenza vaccine Influvac®.

The rates of solicited systemic adverse reactions were similar in recipients of Influvac® Tetra and the non-influenza vaccine, whereby the rates of solicited local adverse reactions were lower in recipients of Influvac® Tetra

b. Tabulated summary of adverse reactions
The following undesirable effects are considered at least possibly related to Influvac® Tetra and have either been observed during the clinical trial with Influvac® Tetra or are resulting from post-marketing experience with Influvac® Tetra and/or the trivalent influenza vaccine Influvac®.

The following frequencies apply:
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).

Adults and elderly

Adverse Reactions Reported with Influvac® Tetra/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		Generalised skin reactions including pruritus, urticaria or non-specific rash
Musculoskeletal and connective tissue disorders		Myalgia, arthralgia		
General disorders and administration site conditions	Fatigue Local reaction: pain	Malaise, shivering Local reactions: redness, swelling, ecchymosis, induration	Fever	
[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] In elderly adults (≥ 61 years) reported as common				

Paediatric population

Children (6 months to 17 years of age) Adverse Reactions Reported with Influvac® Tetra				
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[c] Drowsiness[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[f]			Generalised skin reactions including pruritus, urticaria or non-specific rash
Metabolism and nutrition disorders	Appetite loss[b]			
Gastrointestinal disorders	Nausea[c], abdominal pain[c], diarrhoea[a], vomiting[e]			
Psychiatric disorders	Irritability/fussiness[b]			
Musculoskeletal and connective tissue disorders	Myalgia[c]	Arthralgia[c]		

Informasi untuk Pasien
Influvac® Tetra NH,
suspensi untuk injeksi dalam *pre-filled syringe* 0,5 ml (1 dosis)
Vaksin influenza
Musim 2025/2026

Bacalah seluruh isi leaflet ini dengan cermat sebelum Anda atau anak Anda divaksin, karena vaksin 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® Tetra dan digunakan untuk apa
Influvac® Tetra merupakan vaksin. Vaksin ini membantu dalam melindungi Anda atau anak Anda dari flu (influenza), pada khususnya pada subyek yang menghadapi risiko tinggi yakni komplikasi terkait. Influvac® Tetra diresepkan untuk dewasa dan anak-anak mulai umur 6 bulan. Penggunaan Influvac® Tetra sebaiknya didasarkan pada rekomendasi resmi.

Ketika seseorang diberi vaksin ini, sistem kekebalan (sistem pertahanan alami tubuh) akan menghasilkan 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 jika orang terkena flu adalah selama musim dingin antara Oktober dan Maret. Jika Anda atau anak Anda tidak divaksin pada musim gugur, tentu 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® Tetra akan melindungi Anda atau anak Anda dari empat *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® Tetra
Agar dapat memastikan bahwa Influvac® Tetra cocok untuk Anda atau anak Anda, adalah penting untuk memberitahu dokter atau apoteker Anda atau anak Anda jika salah satu dari poin di bawah ini berkaitan dengan Anda atau anak Anda. Kalau ada hal apa pun yang Anda tidak mengerti, mintalah agar dokter atau apoteker Anda memberikan penjelasan.

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

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

Peringatan dan tindak pencegahan
Anda atau anak Anda sebaiknya memberitahu dokter Anda sebelum vaksinasi jika Anda atau anak Anda memiliki :
- respons kekebalan yang buruk (*immunodeficiency* atau mengkonsumsi obat yang merugikan sistem kekebalan)
- masalah pendarahan atau mudah memar

Dokter Anda akan memutuskan apakah Anda atau anak Anda sebaiknya diberi vaksin.

Pingsan, merasa loyo 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 telah mengalami reaksi semancam ini akibat suntikan sebelumnya.

Jika dengan alasan apapun, Anda atau anak Anda menjalani tes darah dalam waktu beberapa hari sesudah vaksinasi flu, harap beritahu dokter Anda. Hal ini dikarenakan hasil tes darah positif palsu yang ditemukan pada beberapa pasien yang belum lama divaksin.

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

Obat lain dan Influvac® Tetra
- 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.
- Influvac® Tetra boleh diberikan pada waktu yang sama dengan vaksin lain dengan cara menggunakan kaki atau lengan yang satu lagi. Sebaiknya diperhatikan bahwa efek sampingnya kemungkinan lebih kuat.
- Respons perlindungan mungkin berkurang jika diberikan *immunosuppressant*, seperti pengobatan dengan kortikosteroid, obat-obat sitotoksik, atau radioterapi.

Kehamilan dan menyusui
Jika anda hamil atau menyusui, bepikir mungkin anda hamil atau sedang dalam rencana untuk memiliki bayi, konsultasikan dahulu kepada dokter anda sebelum menggunakan Influvac® Tetra. Vaksin flu dapat digunakan dalam semua tahap kehamilan. Menurut data, keamanan lebih besar pada kehamilan trimester kedua dan ketiga daripada trimester pertama. Meskipun demikian, data penggunaan vaksin flu dari seluruh dunia tidak menunjukkan vaksin dapat menyebabkan efek yang membahayakan kehamilan atau janin.

Influvac® Tetra boleh dipakai selama menyusui.

Dokter/apoteker Anda akan memutuskan apakah Anda atau anak Anda sebaiknya diberi Influvac® Tetra. 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 mengoperasikan mesin.

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

3. Bagaimana menggunakan Influvac® Tetra
Penggunaan untuk dewasa
Dewasa mendapatkan satu dosis 0,5 ml.

Penggunaan untuk anak
Anak-anak dari 6 bulan - 17 tahun mendapatkan satu dosis 0,5 ml.
Anak-anak kurang dari 9 tahun yang belum pernah divaksinasi dengan vaksin influenza musiman: dosis kedua harus diberikan setelah paling tidak 4 minggu.
Untuk bayi kurang dari 6 bulan, khasiat dan keamanan Influvac® Tetra belum diketahui.

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 apotekerAnda.

4. Kemungkinan efek samping
Seperti semua obat, Influvac® Tetra mungkin menimbulkan efek samping, walaupun tidak setiap orang mengalaminya.
Hubungi segera dokter Anda kalau 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® Tetra, beberapa efek samping berikut ini telah diamati:

Dewasa dan lansia:
Sangat umum: berpengaruh terhadap lebih dari 1 dalam 10 orang:
- sakit kepala[a]
- keletihan
- reaksi lokal: bagian yang disuntik vaksin (dewasa)

[a] Pada orang tua dewasa (61 tahun keatas) dilaporkan sebagai reaksi umum

General disorders and administration site conditions	Fatigue[c], Fever[f], malaise[c], Local reactions: pain, redness, swelling[g], induration[g]	shivering[d] Local reaction: ecchymosis		

[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] Reported in children 6 months to 5 years of age
[c] Reported in children 6 months to 17 years of age
[d] Reported as common in children 6 to 35 months of age
[e] Reported as a common in children 3 to 5 years of age
[f] Reported as common in children 3 to 17 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

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® Tetra provides active immunisation against four influenza virus strains: an A/(H1N1) strain, an A/(H3N2) strain, and two B strains (one from each lineage; B/(Victoria) and B/(Yamagata)). Influvac® Tetra, manufactured according to the same process as trivalent influenza vaccine Influvac®, induces humoral antibodies against the haemagglutinins. These antibodies neutralise influenza viruses.

Specific levels of hemagglutination-inhibition (HI) antibody titer post-vaccination with inactivated influenza virus vaccines have not been correlated with protection from influenza illness but the HI antibody titers have been used as a measure of vaccine activity. 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:
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 whether the circulating viral strains matched those in the vaccine.

Table : Efficacy in children 6 – 35 months of age

	Influvac® Tetra	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® Tetra compared to 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 noninferiority to trivalent influenza vaccine Influvac® for the postvaccination HI Geometric mean antibody titer (GMT).
In both studies the immune response elicited by Influvac® Tetra against the three strains in common was non-inferior to trivalent influenza vaccine Influvac®. Influvac® Tetra elicited a superior immune response against the additional B strain included in Influvac® Tetra compared 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

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 efficacy 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

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 efficacy 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

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.

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 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
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 container
0.5 ml (single dose) suspension for injection in pre-filled syringe with needle (glass, type I), pack of 1.

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.
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.: DKI1981601943A1

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 v8.0/RDCCDS000649/8
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L034/03/2025

Abbott

Umum: berpengaruh terhadap 1 dalam 10 orang :
- berkeringat
- nyeri otot, nyeri sendi
- pada umumnya merasa tidak enak badan, menggigil
- reaksi lokal: kulit kemerahan, pembengkakan, memar, pengerasan di sekitar bagian tubuh di mana vaksin disuntikkan (lansia)

Tidak Umum: berpengaruh terhadap antara 1 dalam 100 orang:
- demam

Anak 6 bulan -17 tahun:

Efek samping yang terjadi pada anak 6 sampai 35 bulan :
Sangat umum: berpengaruh terhadap lebih dari 1 dalam 10 orang:
- mengantuk
- berkeringat
- hilang nafsu makan
- diare, muntah
- mudah marah/rewel
- reaksi lokal: sakit dan kemerahan

Umum: berpengaruh terhadap 1 dalam 10 orang :
- reaksi local : bengkak, pengerasan pada sekitar bagian yang divaksin (indurasi), lebam pada kulit

Efek samping yang terjadi pada anak 3 – 5 tahun :
Sangat umum : berpengaruh terhadap lebih dari 1 dalam 10 orang :
- mengantuk
- hilang nafsu makan
- mudah marah/rewel
- reaksi local : sakit pada bagian yang di vaksin, kemerahan, bengkak, pengerasan disekitar bagian yang di vaksin (indurasi)

Umum : berpengaruh terhadap 1 dalam 10 orang :
- berkeringat
- diare, muntah
- demam
- reaksi local : lebam pada kulit

Efek samping yang terjadi pada anak 6-17 tahun:
Sangat umum: berpengaruh terhadap lebih dari 1 dalam 10 orang:
- sakit kepala
- mual, nyeri pada bagian perut, diare, muntah
- nyeri otot
- kelelahan, pada umumnya merasa tidak enak badan
- reaksi lokal: kulit kemerahan, pembengkakan, pengerasan di sekitar bagian tubuh di mana vaksin disuntikkan

Umum: berpengaruh terhadap 1 dalam 10 orang:
- berkeringat
- nyeri sendi
- demam
- menggigil
- reaksi lokal: memar

Untuk semua kelompok umur
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.

Di samping efek samping di atas, efek samping berikut terjadi sesekali selama penggunaan umum Influvac® trivalent influenza:

Frekuensi tidak diketahui:
- reaksi kulit yang mungkin menyebar ke seluruh 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, kelainan pada sentuhan, rasa sakit, rasa panas dan dingin, kejang terkait deman, 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 Syndrom*])
- pengurangan sementara jumlah *platelet* yang mengakibatkan memar atau pendarahan yang berlebihan; pembengkakan sementara kelenjar di dalam leher, ketiak, atau selangkangan

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 melaporkanefek samping langsung melalui email: pv.indonesia@abbott.com

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

5. Bagaimana menyimpan Influvac® Tetra

Jauhkan Influvac® Tetra jangan sampai dilihat dan dijangkau oleh anak-anak.
Jangan menggunakan Influvac® Tetra sesudah tanggal habis masa berlakunya, yang tertera di kotak kardus setelah kata "EXP". Kata "bulan" dan kata "tahun" disebutkan. Tanggal habis masa berlakunya 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® Tetra berisi apa
Beberapa zat aktif di dalam Influvac® Tetra adalah:
Influenza virus surface antigens (inactivated) (haemagglutinin and neuraminidase) dalam beberapa *strain** berikut ini:

- A/Victoria/4897/2022(H1N1)pdm09-like virus (A/Victoria/4897/2022, IVR-238)	15 mikrogram HA **
- A/Croatia/10136RV/2023 (H3N2)-like virus (A/Croatia/10136RV/2023, X-425A)	15 mikrogram HA **
- B/Austria/1359417/2021-like virus (B/Austria/1359417/2021, BVR-26)	15 mikrogram HA **
- B/Phuket/3073/2013-like virus (B/Phuket/3073/2013, wild type)	15 mikrogram HA **
	per 0,5 ml dosis.

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

Vaksin ini mematuhi rekomendasi *World Health Organisation (WHO) (northern hemisphere)* dan rekomendasi Uni Eropa untuk **musim 2025/2026.**
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® Tetra dan isi kemasannya
Influvac® Tetra 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.: DKI1981601943A1

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

Dikemas dan dirilis oleh:
Abbott Biologicals B.V.
Veerweg 12, 8121 AA Olst, The Netherlands

Pendaftar:
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Jl. Raya Jakarta Bogor Km. 37, Depok, Indonesia

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