PACKAGE LEAFLET: INFORMASI UNTUK PASIEN

Fluarix Tetra

Quadrivalent influenza vaccine (split virion, inactivated)

Untuk periode penggunaan SH 2026

Baca Leaflet Ini Dengan Saksama Sebelum Anda atau Anak Anda Mendapatkan Vaksin Ini.
- Simpan leaflet ini. Anda mungkin butuh untuk membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, Anda dapat menghubungi dokter atau apoteker Anda.
- Vaksin ini diresepkan untuk Anda atau anak Anda. Jangan diberikan untuk orang lain.
- Jika ada kejadian ikutan pasca imunisasi (KIPI) yang menjadi serius atau jika Anda mengalami KIPI yang tidak tercantum pada leaflet ini, harap hubungi dokter Anda.

Leaflet ini ditujukan bagi orang yang menerima vaksin ini, tetapi vaksin ini dapat diberikan kepada remaja dan anak-anak sehingga Anda mungkin membaca leaflet ini untuk anak Anda.

Pada Leaflet Ini:

1. Apakah *Fluarix Tetra* Itu dan Digunakan untuk Apa

Fluarix Tetra adalah vaksin *quadrivalent* untuk digunakan pada orang dewasa dan anak-anak dari usia 6 bulan untuk mencegah influenza (flu) yang disebabkan oleh virus influenza tipe A dan B yang terdapat dalam vaksin.

Influenza (flu) adalah penyakit saluran napas bagian atas dan paru yang disebabkan oleh infeksi virus flu. Gejala influenza yang paling umum adalah suhu tinggi, sakit tenggorokan, batuk, nyeri dan nyeri umum, sakit kepala, lemas, dan kelelahan. Komplikasi dapat terjadi terutama pada seseorang yang sangat muda, sangat tua, dan mereka yang memiliki kekebalan buruk terhadap infeksi.

Ketika seseorang divaksinasi dengan ***Fluarix Tetra***, sistem kekebalan tubuh (sistem pertahanan alami tubuh) akan membuat antibodi untuk melindungi orang tersebut agar tidak terinfeksi oleh jenis virus influenza tertentu***. Fluarix Tetra*** hanya efektif melawan infeksi oleh tipe virus A dan B dan jenis virus yang terkait erat sebagaimana vaksin tersebut dirancang. Tidak satu pun dari bahan-bahan dalam vaksin dapat menyebabkan influenza.

Seperti halnya semua vaksin, ***Fluarix Tetra*** tidak sepenuhnya melindungi semua orang yang divaksinasi.

2. Apa yang Perlu Anda Ketahui Sebelum Mendapatkan *Fluarix Tetra*

***Fluarix Tetra* tidak boleh diberikan:**
- Jika Anda alergi (hipersensitif) terhadap ***Fluarix Tetra***, atau vaksin influenza atau bahan lain yang terkandung dalam ***Fluarix Tetra***. Zat aktif dan bahan lain dalam ***Fluarix Tetra*** tercantum pada *Bagian 5* dari leaflet. Tanda-tanda reaksi alergi dapat meliputi ruam pada kulit disertai rasa gatal, sesak napas, dan pembengkakan pada wajah atau lidah. **Temui dokter Anda segera jika Anda mengalami salah satu gejala ini.**

Peringatan dan tindakan pencegahan

Dokter Anda perlu mengetahui hal berikut sebelum Anda mulai divaksinasi:
- Jika Anda mengalami infeksi berat dengan panas tinggi. Pada kasus ini, vaksinasi akan ditunda sampai kondisi membaik. Infeksi ringan seperti pilek seharusnya tidak menjadi masalah, bagaimanapun konsultasikan dengan dokter Anda terlebih dahulu.
- Jika Anda memiliki masalah pendarahan atau mudah memar.

Jika Anda memiliki sistem kekebalan tubuh yang lemah, seperti karena infeksi HIV atau karena obat-obatan yang mempengaruhi sistem kekebalan, Anda mungkin tidak akan mendapatkan perlindungan sepenuhnya dari ***Fluarix Tetra***.

Pingsan dapat terjadi setelah, atau bahkan sebelum suntikan, oleh karena itu beri tahu dokter atau perawat jika Anda pingsan pada penyuntikan sebelumnya.

Pasien dengan riwayat *Guillain-Barré Syndrome* (GBS) dengan onset 6 minggu sejak vaksinasi memungkinkan peningkatan risiko terhadap GBS jika diberikan vaksin influenza. Risiko tersebut harus ditimbang terhadap manfaatnya kepada masing-masing pasien vaksinasi influenza.

Sebagai pasien dengan riwayat GBS memiliki kemungkinan peningkatan sindrom, kemungkinan mereka dalam peningkatan sindrom terhadap vaksinasi influenza mungkin lebih tinggi dari individu yang tidak memiliki riwayat GBS.

Obat lain dan *Fluarix Tetra*
Fluarix Tetra dapat digunakan bersamaan dengan vaksin pneumokokal, vaksin *herpes zoster (**Shingrix**)* dan vaksin COVID-19 mRNA.

Beritahu dokter Anda jika Anda sedang atau baru saja selesai menggunakan obat lain, termasuk obat yang didapatkan tanpa resep atau vaksin lain.

Fluarix Tetra dapat mempengaruhi hasil pemeriksaan laboratorium untuk diagnosis penyakit, misalnya HIV dan hepatitis. Informasikan kepada dokter/laboratorium bila Anda telah mendapatkan vaksin ini dan berencana untuk melakukan pemeriksaan laboratorium.

Kehamilan dan menyusui
Konsultasikan dengan dokter Anda sebelum divaksinasi dengan ***Fluarix Tetra***.

Vaksin dapat diberikan kepada ibu hamil setelah dilakukan penilaian terhadap risiko dan manfaatnya.

Keamanan ***Fluarix Tetra*** jika diberikan pada ibu hamil belum dievaluasi dalam uji klinis.

Ketika diberikan selama kehamilan, data keamanan pada vaksin *inactivated seasonal influenza* berdasarkan tinjauan literatur sistematis, dan data pascapemasaran yang tersedia untuk ***Fluarix Tetra***, tidak menunjukkan hasil peningkatan risiko kehamilan yang merugikan.

Studi pada hewan tidak menyebabkan efek yang berbahaya pada kehamilan.

Keamanan ***Fluarix Tetra*** jika diberikan pada ibu menyusui belum diketahui. Hingga saat ini belum diketahui apakah ***Fluarix Tetra*** dikeluarkan melalui ASI.

Fluarix Tetra sebaiknya hanya digunakan selama menyusui jika kemungkinan manfaatnya lebih besar daripada risiko potensialnya.

3. Bagaimana Cara Pemberian *Fluarix Tetra*

Fluarix Tetra diberikan sebagai satu suntikan 0,5 mL ke dalam otot.

Anak-anak usia 6 bulan sampai kurang dari 9 tahun yang belum pernah mendapatkan vaksinasi influenza sebelumnya, harus diberikan dosis kedua minimum 4 minggu setelah dosis pertama.

4. Kemungkinan Kejadian Ikutan Pasca Imunisasi (KIPI)

Seperti obat-obatan lain, ***Fluarix Tetra*** dapat menyebabkan KIPI, walaupun tidak semua orang akan mengalami KIPI. KIPI berikut ini dapat terjadi dengan pemberian vaksin ini:

KIPI yang terjadi pada anak usia 6-36 bulan
Sangat umum:
- kehilangan nafsu makan
- iritabilitas
- merasa mengantuk
- sakit pada tempat pemberian vaksin
- kemerahan pada tempat pemberian vaksin.

Umum:
- demam (≥38.0°C)

- bengkak pada tempat pemberian vaksin.

KIPI yang terjadi pada anak usia 3-6 tahun
Sangat umum:
- sakit pada tempat pemberian vaksin
- kemerahan pada tempat pemberian vaksin
- bengkak pada tempat pemberian vaksin
- iritabilitas.

Umum:
- kehilangan nafsu makan
- merasa mengantuk
- demam (≥38.0°C)
- indurasi (pembengkakan) pada tempat suntikan.

Tidak umum:
- ruam
- gatal pada tempat suntikan.

KIPI yang terjadi pada anak usia 6-18 tahun
Sangat umum:
- nyeri otot
- sakit pada tempat pemberian vaksin
- kemerahan pada tempat pemberian vaksin
- bengkak pada tempat pemberian vaksin
- merasa lelah.

Umum:
- masalah pada lambung dan pencernaan (termasuk mual, muntah, diare, sakit perut)
- sakit kepala
- nyeri sendi
- menggigil
- demam (≥38.0°C)
- indurasi (pembengkakan) pada tempat suntikan.

Tidak umum:
- ruam
- gatal pada tempat suntikan.

KIPI yang terjadi pada dewasa ≥18 tahun
Sangat umum:
- sakit pada tempat pemberian vaksin
- merasa lelah
- nyeri otot.

Umum:
- kemerahan dan bengkak pada tempat pemberian vaksin
- menggigil
- demam
- sakit kepala
- masalah pada lambung dan pencernaan (termasuk mual, muntah, diare, sakit perut)
- nyeri sendi
- berkeringat berlebihan.

Tidak umum:
- lebam dan gatal pada tempat suntikan
- pusing.

Selain itu, KIPI yang terjadi selama studi klinis pada subjek dari usia 3 tahun dengan vaksin influenza lain (***Fluarix***) adalah:
Umum:
- benjolan keras pada tempat suntikan

- berkeringat.

KIPI berikut tidak terjadi selama studi klinis tetapi telah dilaporkan sesekali selama penggunaan umum ***Fluarix*** (vaksin influenza trivalen) dan/atau ***Fluarix Tetra***:
Jarang:

- Reaksi alergi (termasuk reaksi anafilaksis), meliputi: ruam disertai gatal pada tangan dan kaki, pembengkakan mata dan wajah, kesulitan bernafas atau menelan, penurunan tekanan darah dan kehilangan kesadaran secara mendadak.
  Reaksi-reaksi ini biasanya terjadi sebelum meninggalkan ruang praktik dokter. Namun, jika Anda mengalami gejala-gejala ini, segera konsultasikan kepada dokter.
- Peradangan saraf (*neuritis*), peradangan otak dan sumsum tulang belakang (*encephalomyelitis*), peradangan sementara pada saraf, menyebabkan rasa sakit, kelemahan, dan kelumpuhan yang disebut *Guillain-Barré Syndrome* (GBS).
- Reaksi kulit yang dapat menyebar ke seluruh tubuh termasuk gatal (pruritus, urtikaria) dan kemerahan pada kulit (eritema).
- Pembengkakan sementara pada kelenjar di leher, ketiak atau selangkangan (*transient lymphadenopathy*).
- Gejala mirip flu, umumnya terasa tidak enak badan.

Pelaporan kejadian ikutan pasca imunisasi (KIPI)
Jika Anda mengalami KIPI, harap konsultasikan ke dokter, apoteker, atau perawat, termasuk kemungkinan KIPI lain yang tidak tertulis dalam informasi ini.

Jika KIPI menjadi serius, atau jika Anda melihat terdapat KIPI yang tidak tercantum dalam brosur ini, segera konsultasikan pada dokter atau apoteker Anda.

Laporkan Kejadian Tidak Diinginkan (KTD) ke GSK Indonesia melalui situs web https://gsk.public.reportum.com.

5. Informasi Lain

Jenis-jenis antigen influenza dalam vaksin dapat berubah dari satu tahun ke tahun lainnya. Setiap tahun, *World Health Organization* (WHO) merekomendasikan jenis antigen influenza untuk digunakan dalam vaksin ini. Keputusan ini didasarkan pada jenis-jenis virus influenza yang paling mungkin terjadi selama musim flu berikutnya.

Setiap dosis vaksin 0,5 mL mengandung 15 mikrogram *haemagglutinin* dari masing-masing jenis antigen influenza.

Apa kandungan *Fluarix Tetra*
Zat aktif: Influenza virus (*inactivated, split*) dari *strain**:

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**
B/Phuket/3073/2013-*like strain* (B/Phuket/3073/2013, wild type)	15 *micrograms* HA**

tiap 0.5 mL dosis
** propagated in fertilised hens' eggs from healthy chicken flocks.*
*** haemagglutinin.*

Bahan lain: *sodium chloride, disodium phosphate dodecahydrate, potassium dihydrogen phosphate, potassium chloride, magnesium chloride hexahydrate, α-tocopheryl hydrogen succinate, polysorbate 80, octoxinol 10* dan *water for injections.*

Residu: *hydrocortisone, gentamicin sulphate, ovalbumin, formaldehyde,* dan *sodium deoxycholate.*

Bagaimana cara penyimpanan *Fluarix Tetra*

- Jauhkan dari jangkauan dan pandangan anak-anak.
- Jangan gunakan ***Fluarix Tetra*** setelah tanggal kedaluwarsa yang tertera pada karton. Tanggal kedaluwarsa mengacu pada tanggal terakhir dalam bulan tersebut.
- Simpan dalam lemari es (2°C – 8°C).
- Simpan dalam kemasan asli untuk melindungi dari cahaya.
- Jangan buang sisa vaksin melalui air limbah atau limbah rumah tangga. Tanyakan pada apoteker Anda bagaimana cara membuang vaksin. Langkah-langkah ini membantu melindungi lingkungan.

Bagaimana bentuk dari *Fluarix Tetra* dan isi kemasan
Pemerian: suspensi tidak berwarna hingga sedikit opalesen.

Tersedia dalam dosis tunggal *pre-filled syringe* (*type I glass*) 0,5 mL – kemasan 1.

Tidak semua kemasan tersedia di setiap negara.

HARUS DENGAN RESEP DOKTER

Dus, 1 *pre-filled syringe* @ 0,5 mL dengan jarum Reg. No. DKI2197100743A1

Produsen yang bertanggung jawab untuk rilis bets
GlaxoSmithKline Biologics, Branch of SmithKline Beecham Pharma GmbH & Co. KG
Dresden, Germany.

Diimpor oleh
PT Glaxo Wellcome Indonesia
Jakarta, Indonesia.

Version number	: 04
Reference	: GDS08/IPI21 – ASU 2026 + Co-admin update
Date of local revision	: 12 November 2025

FLUARIX TETRA

Quadrivalent influenza vaccine (split virion, inactivated), suspension for injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

Fluarix Tetra is an inactivated influenza vaccine (split virion), containing antigens (propagated in embryonated eggs) equivalent to the following strains:

A/Missouri/11/2025 (H1N1)pdm09-like strain (A/Switzerland/6849/2025, IVR-278);
A/Singapore/GP20238/2024 (H3N2)-like strain (A/Singapore/GP20238/2024, IVR-277);
B/Austria/1359417/2021-like strain (B/Austria/1359417/2021, BVR-26);
B/Phuket/3073/2013-like strain (B/Phuket/3073/2013, wild type).

This vaccine complies with the WHO recommended strains (Southern Hemisphere) for the season 2026.

Each 0.5 mL vaccine dose contains 15 µg haemagglutinin of each of the recommended strains.

Fluarix Tetra meets the WHO requirements for biological substances and influenza vaccines and the European Pharmacopoeia requirements for influenza vaccines.

CLINICAL INFORMATION

Indications

Fluarix Tetra is a quadrivalent vaccine indicated for active immunization of children & adolescents from 6 months of age, adult with high risk factor (>18 years old), and elderly (>60 years old) for the prevention of influenza disease caused by influenza virus types A and B contained in the vaccine (see *Pharmacodynamics*).

The use of ***Fluarix Tetra*** should be based on official recommendations.

Dosage and Administration

Fluarix Tetra should be administered as a single 0.5 mL injection.

Children 6 months to less than 9 years of age who have not previously been vaccinated against influenza should receive a second dose of 0.5 mL after an interval of at least 4 weeks.

Children aged <6 months

The safety and efficacy of ***Fluarix Tetra*** in children aged less than 6 months have not been established.

Vaccination should be carried out by intramuscular injection preferably into the deltoid muscle or anterolateral thigh (depending on the muscle mass).

Contraindications

Fluarix Tetra should not be administered to subjects with known hypersensitivity after previous administration of ***Fluarix Tetra*** or influenza vaccines or to any component of the vaccine.

Warnings and Precautions

It is good clinical practice to precede vaccination by a review of the medical history (especially with regards to previous vaccination and possible occurrence of undesirable events) and a clinical examination.

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.

As with other vaccines, vaccination with ***Fluarix Tetra*** should be postponed in subjects suffering from an acute severe febrile illness. The presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

It may be expected that in patients receiving immunosuppressive treatment or patients with immunodeficiency, an adequate immune response may not be elicited.

Fluarix Tetra is not effective against all possible strains of influenza virus. ***Fluarix 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.

FLUARIX TETRA SHOULD UNDER NO CIRCUMSTANCES BE ADMINISTERED INTRAVASCULARLY.

As with other vaccines administered intramuscularly, ***Fluarix 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.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

Patients with a history of Guillain-Barré syndrome (GBS) with an onset within six weeks of an influenza vaccination may be at increased risk of again developing GBS if given influenza vaccine. Such risk should be weighed against the benefits to the individual patient of influenza vaccination.

As patients with a history of GBS have an increased likelihood of again developing the syndrome, the chance of them coincidentally developing the syndrome following influenza vaccination may be higher than individuals with no history of GBS.

Interactions
Fluarix Tetra can be concomitantly administered with pneumococcal vaccines or adjuvanted herpes zoster vaccine (*Shingrix*) or coronavirus disease 2019 (COVID-19) messenger ribonucleic acid (mRNA) vaccines (see *Pharmacodynamics*).

Incidence of fatigue, headache, myalgia, arthralgia, gastrointestinal symptoms (including nausea, vomiting, diarrhoea and/or abdominal pain), and shivering reported in subjects vaccinated concomitantly with ***Fluarix Tetra*** and *Shingrix* is similar to that observed with *Shingrix* alone, and higher compared to ***Fluarix Tetra*** alone.

If ***Fluarix Tetra*** is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites.

False positive ELISA serologic tests for HIV-1, Hepatitis C, and especially HTLV-1 may occur following influenza vaccination. These transient false-positive results may be due to cross-reactive IgM elicited by the vaccine. For this reason, a definitive diagnosis of HIV-1, Hepatitis C, or HTLV-1 infection requires a positive result from a virus-specific confirmatory test (e.g. Western Blot or immunoblot).

Pregnancy and Lactation
The vaccine may be administered to pregnant women following an assessment of the risks and benefits.

The safety of ***Fluarix Tetra*** when administered to pregnant women has not been evaluated in clinical trials.

When administered during pregnancy, safety data on inactivated seasonal influenza vaccines based on systematic literature review, and available post-marketing data on ***Fluarix Tetra***, do not indicate an increased risk of adverse pregnancy outcomes.

Animal studies with ***Fluarix Tetra*** do not indicate direct or indirect harmful effects with respect to reproductive and developmental toxicity (see *Non-clinical Information*).

The safety of ***Fluarix Tetra*** when administered to breast-feeding women has not been evaluated. It is unknown whether ***Fluarix Tetra*** is excreted in human breast milk.

Fluarix Tetra should only be used during breast-feeding when the possible advantages outweigh the potential risks.

Adverse Reactions
Adverse reactions reported for ***Fluarix Tetra*** are listed according to the following frequency categories:
Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)

Clinical trial data
Adults
A study with ***Fluarix Tetra*** in adults has evaluated the incidence of adverse reactions in subjects ≥18 years who received one dose of ***Fluarix Tetra*** (N=3,036) or ***Fluarix*** (N=1,010).

The following adverse reactions per dose have been reported:

Adverse Reactions	Frequency
Myalgia, injection site pain, fatigue	Very common
Headache, gastrointestinal symptoms (including nausea, vomiting, diarrhoea and/or abdominal pain), sweating[1], arthralgia, injection site redness, injection site swelling, shivering, fever, injection site induration[1]	Common
Dizziness[2], injection site hematoma[2], injection site pruritus[2]	Uncommon

[1]Reported in previous ***Fluarix*** trials
[2]Reported as unsolicited adverse reaction

Children aged 6 months to <18 years
Two clinical studies evaluated the reactogenicity and safety of ***Fluarix Tetra*** in children who received at least one dose of ***Fluarix Tetra*** or a control vaccine.

One study enrolled children 3 to <18 years of age who received ***Fluarix Tetra*** (N= 915) or ***Fluarix*** (N= 912). The second study enrolled children 6 to <36 months of age who received ***Fluarix Tetra*** (N= 6,006) or a non-influenza vaccine control (N= 6,012) (see *Pharmacodynamics*).

The following adverse reactions per dose have been reported:

Adverse reactions	Frequency		
	6 to <36 months	3 to <6 years	6 to <18 years
Loss of appetite	Very common	Common	N/A
Irritability/Fussiness	Very common	Very common	N/A
Drowsiness	Very common	Common	N/A
Headache	N/A	N/A	Common
Gastrointestinal symptoms (including nausea, diarrhoea, vomiting and/or abdominal pain)	N/A	N/A	Common
Rash[1]	N/R	Uncommon	Uncommon
Myalgia	N/A	N/A	Very common
Arthralgia	N/A	N/A	Common
Fever (≥38.0°C)	Common	Common	Common
Fatigue	N/A	N/A	Very common
Injection site pain	Very common	Very common	Very common
Injection site redness	Very common	Very common	Very common
Injection site swelling	Common	Very common	Very common
Shivering	N/A	N/A	Common
Injection site pruritus[1]	N/R	Uncommon	Uncommon
Injection site induration[2]	N/A	Common	Common

N/A= Not solicited in this age group.
N/R= Not reported.
[1]Reported as unsolicited adverse reaction.
[2]Reported in previous ***Fluarix*** trials.

Post-marketing data
The following adverse reactions have been observed for ***Fluarix*** and/or ***Fluarix Tetra*** during post-marketing surveillance[1].

Adverse reactions	Frequency
Transient lymphadenopathy, allergic reactions (including anaphylactic reactions), neuritis, acute disseminated encephalomyelitis, Guillain-Barré syndrome (GBS)[2], urticaria, pruritus, erythema, angioedema, influenza-like illness, malaise	Rare

[1]Three of the influenza strains contained in ***Fluarix*** are included in ***Fluarix Tetra***.
[2]Spontaneous reports of GBS have been received following vaccination with ***Fluarix*** and ***Fluarix Tetra***; however, a causal association between vaccination and GBS has not been established.

Adverse events should be reported to GSK Indonesia via website https://gsk.public.reportum.com and Pusat Farmakovigilans/MESO Nasional Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif Badan Pengawas Obat dan Makanan.
Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Phone: +62-21-4244691 Ext.1079
Website: https://e-meso.pom.go.id/ADR

PHARMACOLOGICAL PROPERTIES

Pharmacodynamics

Mechanism of Action

Fluarix Tetra induces haemagglutination-inhibition (HI) antibodies against the 4 influenza virus strains contained in the vaccine. While specific levels of HI antibody in response to inactivated influenza virus vaccines have not been correlated with protection from influenza illness the HI antibody titres have been used as a measure of vaccine activity. In some human challenge studies, HI antibody titres of ≥1:40 have been associated with protection from influenza illness in up to 50% of subjects.

Annual revaccination with the current vaccine is recommended because immunity declines during the year after vaccination, and because circulating strains of influenza virus might change from year to year.

Pharmacodynamic Effects

Efficacy in children 6-35 months of age:

The vaccine efficacy (VE) of ***Fluarix Tetra*** was evaluated in study D-QIV-004, a randomized, observer-blind, non-influenza vaccine-controlled trial conducted during influenza seasons 2011 to 2014. Healthy subjects aged 6 through 35 months were randomized (1:1) to receive ***Fluarix Tetra*** (N= 6,006) or an age appropriate non-influenza control vaccine (N= 6,012). Subjects were administered 1 dose (in case of history of influenza vaccination) or 2 doses, approximately 28 days apart.

VE of ***Fluarix Tetra*** was assessed for the prevention of influenza A and/or B disease (moderate to severe and of any severity) due to any seasonal influenza strain, starting 2 weeks post-vaccination until the end of the influenza season (approximately 6 months later). ***Fluarix Tetra*** met the predefined criteria for primary and secondary VE objectives (Table 1).

Table 1: Attack rates and VE in children 6-35 months of age (ATP (according to protocol) cohort for efficacy – time to event).

	Fluarix Tetra **(N= 5,707)**	**Active comparator (N= 5,697)**	**Vaccine efficacy**	
	Attack rate (%)	**Attack rate (%)**	**%**	**CI**
Any severity influenza[1]				
RT-PCR[3] confirmed	6.03	11.62	49.8	41.8; 56.8[4]
Culture confirmed	5.31	10.57	51.2	44.1; 57.6[5]
Culture confirmed vaccine matching strains	1.54	3.79	60.1	49.1; 69.0[5]
Moderate to severe influenza[2]				
RT-PCR[3] confirmed	1.58	4.25	63.2	51.8; 72.3[4]
Culture confirmed	1.38	3.79	63.8	53.4; 72.2[5]
Culture confirmed vaccine matching strains	0.35	1.54	77.6	64.3; 86.6[5]
Lower respiratory illness RT-PCR confirmed	0.49	1.07	54.0	28.9; 71.0[5]
Acute otitis media RT PCR-confirmed	0.21	0.49	56.6	16.7; 78.8[5]

[1]Defined as an episode of influenza-like illness (ILI, i.e. fever ≥38°C with any of the following: cough, runny nose, nasal congestion, or breathing difficulty) or a consequence of influenza virus infection [acute otitis media (AOM) or lower respiratory illness (LRI)].
[2]Defined as a subset of any influenza disease, with any of the following: fever >39°C, physician-diagnosed AOM, physician-diagnosed lower respiratory tract infection, physician-diagnosed serious extra-pulmonary complications, hospitalisation in the intensive care unit, or supplemental oxygen required for more than 8 hours.
[3]reverse transcription polymerase chain reaction.
[4]2-sided 97.5% confidence interval.
[5]2-sided 95% confidence interval.

Exploratory analyses were conducted on the Total Vaccinated Cohort (TVC) including 12,018 subjects. ***Fluarix Tetra*** was efficacious in the prevention of moderate to severe influenza caused by each of the 4 strains (Table 2), even when there was significant antigenic mismatch with 2 of the vaccine strains (A/H3N2 and B/Victoria).

Table 2: Attack rates and VE for RT-PCR confirmed moderate to severe disease by Influenza A subtypes and Influenza B lineages in children 6-35 months of age (TVC)

Strain	***Fluarix Tetra* (N=6,006)**	**Active comparator (N=6,012)**	**Vaccine Efficacy**	
	Attack rate (%)	**Attack rate (%)**	**%**	**95% CI**
A/H1N1[1]	0.22	0.77	72.1	49.9; 85.5
A/H3N2[2]	0.88	1.86	52.7	34.8; 66.1
B/Victoria[3]	0.05	0.25	80.1	39.7; 95.4
B/Yamagata[4]	0.37	1.21	70.1	52.7; 81.9

[1 to 4]Proportion of antigenic matching strains was 84.8%, 2.6%, 14.3% and 66.6%, for A/H1N1, A/H3N2, B/Victoria, and B/Yamagata, respectively.

Additionally, for RT-PCR confirmed cases of any severity, ***Fluarix Tetra*** reduced the risk of visits to the general practitioner by 47% (Relative Risk (RR): 0.53 [95% CI: 0.46; 0.61], i.e., 310 versus 583 visits) and to the emergency room by 79% (RR: 0.21 [95% CI: 0.09; 0.47], i.e., 7 versus 33 visits). The use of antibiotics was reduced by 50% (RR: 0.50 [95% CI: 0.42; 0.60], i.e., 172 versus 341 subjects).

Immunogenicity in children and adults:
Immunogenicity of ***Fluarix Tetra*** was evaluated in terms of HI Geometric mean antibody titre (GMT) at 28 days after the last dose (children) or Day 21 (adults) and HI seroconversion rate (4-fold rise in reciprocal titre or change from undetectable [<10] to a reciprocal titre of ≥40).

In study D-QIV-004, the evaluation was performed in a sub-cohort of 1,332 children (Table 3).

The effect of a 2-dose priming schedule in D-QIV-004 was evaluated by assessing the immune response after revaccination one year later with 1 dose of ***Fluarix Tetra*** in study D-QIV-009. This study demonstrated that 7 days post-vaccination, immune memory in children 6 to 35 months of age had been elicited for all 4 vaccine strains.

Immunogenic non-inferiority of ***Fluarix Tetra*** was assessed versus ***Fluarix*** in children (study D-QIV-003) and in adults (study D-QIV-008). Children received 1 or 2 doses and adults received 1 dose of either vaccine. In both studies, ***Fluarix Tetra*** elicited an immune response against the 3 strains in common that was non-inferior to ***Fluarix*** and a superior immune response against the additional B strain included in ***Fluarix Tetra*** (Table 3).

Table 3: Post-vaccination GMT and seroconversion rates (SCR) in children (6-35 months; 3 to <18 years) and adults ≥18 years (ATP (95% CI)).

Children 6 to 35 months of age (D-QIV-004)				
	Fluarix Tetra		**Control**	
	N=750-753	**N'=742-746**	**N=578-579**	**N'=566-568**
	GMT[1]	**SCR[1]**	**GMT[1]**	**SCR[1]**
A/H1N1	165.3 (148.6;183.8)	80.2% (77.2;83.0)	12.6 (11.1;14.3)	3.5% (2.2;5.4)
A/H3N2	132.1 (119.1;146.5)	68.8% (65.3;72.1)	14.7 (12.9;16.7)	4.2% (2.7;6.2)
B (Victoria)	92.6 (82.3;104.1)	69.3% (65.8;72.6)	9.2 (8.4;10.1)	0.9% (0.3;2.0)

B (Yamagata)	121.4 (110.1;133.8)	81.2% (78.2;84.0)	7.6 (7.0;8.3)	2.3% (1.2;3.9)
Children 3 to <18 years (D-QIV-003)				
	Fluarix Tetra		***Fluarix[2]***	
	N=791	**N'=790**	**N=818**	**N'=818**
	GMT	**SCR**	**GMT**	**SCR**
A/H1N1	386.2 (357.3;417.4)	91.4% (89.2;93.3)	433.2 (401.0;468.0)	89.9% (87.6;91.8)
A/H3N2	228.8 (215.0;243.4)	72.3% (69.0;75.4)	227.3 (213.3;242.3)	70.7% (67.4;73.8)
B (Victoria)	244.2 (227.5;262.1)	70.0% (66.7;73.2)	245.6 (229.2;263.2)	68.5% (65.2;71.6)
B (Yamagata)	569.6 (533.6;608.1)	72.5% (69.3;75.6)	224.7 (207.9;242.9)	37.0% (33.7;40.5)
Adults ≥18 years (D-QIV-008)				
	Fluarix Tetra		***Fluarix[2]***	
	N=1,809	**N'=1,801**	**N=608**	**N'=605**
	GMT	**SCR**	**GMT**	**SCR**
A/H1N1	201.1 (188.1;215.1)	77.5% (75.5;79.4)	218.4 (194.2;245.6)	77.2% (73.6;80.5)
A/H3N2	314.7 (296.8;333.6)	71.5% (69.3;73.5)	298.2 (268.4;331.3)	65.8% (61.9;69.6)
B (Victoria)	404.6 (386.6;423.4)	58.1% (55.8;60.4)	393.8 (362.7;427.6)	55.4% (51.3;59.4)
B (Yamagata)	601.8 (573.3;631.6)	61.7% (59.5;64.0)	386.6 (351.5;425.3)	45.6% (41.6;49.7)

N= Number of subjects with post-vaccination results available (for GMT).
N'= Number of subjects with both pre- and post-vaccination results available (for SCR).
[1]results from the immunogenicity subcohort.
[2]B (Yamagata) strain was not included in ***Fluarix.***

Concomitant administration with pneumococcal vaccines:
In clinical study D-QIV-010 involving 356 adults ≥50 years of age at risk for complications of influenza and pneumococcal diseases, subjects received ***Fluarix Tetra*** and 23-valent pneumococcal polysaccharide vaccine (PPV23) either concomitantly or separately. For all 4 ***Fluarix Tetra*** vaccine strains and the 6 pneumococcal serotypes (1, 3, 4, 7F, 14, and 19A) in PPV23 evaluated in the pre-specified primary analysis, the immune response was non-inferior between the 2 groups. Based on a descriptive analysis for 6 additional pneumococcal vaccine serotypes (5, 6B, 9V, 18C, 19F, and 23F), the immune response was comparable between groups, with 91.7% to 100% and 90.7% to 100% of subjects attaining seroprotective antibody levels against these serotypes in the separate and concomitant administration group respectively.

Immunological non-inferiority has been demonstrated based on published data for all 3 ***Fluarix*** trivalent strains (D-TIV) and all 13-valent pneumococcal conjugate vaccine (PCV13) serotypes in adults 50-59 years of age, as well as for 2 of 3 D-TIV strains and 12 of 13 PCV13 serotypes in adults >65 years of age. A lower immune response to some pneumococcal serotypes was observed when PCV13 was given concomitantly with D-TIV as compared to separate administration, however the clinical relevance of this observation is unknown.

Concomitant administration with adjuvanted herpes zoster vaccine (*Shingrix*):
In clinical study Zoster-004, 828 adults ≥50 years of age were randomized to receive 2 doses of *Shingrix* 2 months apart, administered either concomitantly at the first dose (N=413) or non-concomitantly (N=415) with one dose of ***Fluarix Tetra***. The antibody responses to each vaccine were similar, whether administered concomitantly or non-concomitantly. Furthermore, immunological non-inferiority between concomitant and non-concomitant administration was demonstrated for all four strains included in ***Fluarix Tetra*** in terms of HI antibody GMTs.

Concomitant administration with COVID-19 mRNA vaccine:
In clinical study Zoster-091, 988 adults ≥18 years of age received ***Fluarix Tetra*** and monovalent COVID-19 mRNA-1273 booster (50 micrograms) vaccine (original SARS-CoV-2 strain) either concomitantly (N=498) or non-concomitantly, administered two weeks apart (N=490). The antibody responses to each vaccine were similar, regardless of administration schedule. Immunological non-

inferiority between concomitant and non-concomitant administration was demonstrated for all four strains included in ***Fluarix Tetra*** in terms of HI antibody GMTs, and for the COVID-19 mRNA-1273 booster vaccine in terms of anti-S protein antibody GMC.

Non-clinical Information
Non-clinical data reveal no special hazards for humans based on conventional studies of acute toxicity, local tolerance, repeated dose toxicity and reproductive/developmental toxicity.

PHARMACEUTICAL INFORMATION
List of Excipients
Sodium chloride, disodium phosphate dodecahydrate, potassium dihydrogen phosphate, potassium chloride, magnesium chloride hexahydrate, α-tocopheryl hydrogen succinate, polysorbate 80, octoxinol 10 and water for injections.

Hydrocortisone, gentamicin sulphate, ovalbumin, formaldehyde and sodium deoxycholate are present as residues from the manufacturing process.

Shelf Life
12 months.

Storage
Store at 2°C - 8°C (in a refrigerator).
Do not freeze.
Store in the original package in order to protect from light.
The storage conditions are detailed on the packaging.

Nature and Contents of Container
0.5 mL of suspension in a pre-filled syringe (type I glass) with a plunger stopper (butyl rubber) and with a rubber tip cap. The tip cap and rubber plunger stopper of the pre-filled syringe are not made with natural rubber latex.

Pack sizes of 1, with or without needles.

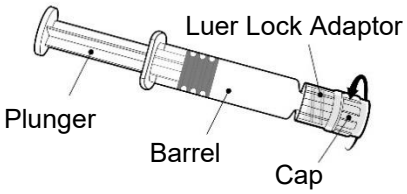
Not all presentations are available in every country.

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

Use and Handling
The vaccine presents as a colourless to slightly opalescent suspension.

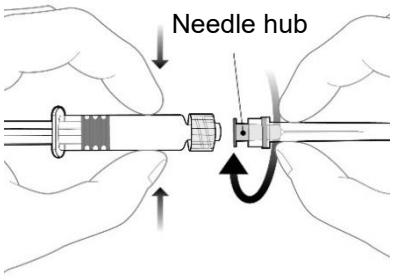
The syringe should be shaken and inspected visually for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, discard the vaccine.

Instructions for the pre-filled syringe



Hold the syringe by the barrel, not by the plunger.

Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, connect the hub to the Luer Lock Adaptor and rotate a quarter turn clockwise until you feel it lock.

Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

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

Presentations
Box, 1 pre-filled syringe @ 0.5 mL with needle Reg. No. DKI2197100743A1

HARUS DENGAN RESEP DOKTER

Manufacturer responsible for batch release
GlaxoSmithKline Biologicals, Branch of SmithKline Beecham Pharma GmbH & Co. KG,
Dresden, Germany
Tel: (49) 351 45610.

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Jakarta, Indonesia.

Version number : 05
Reference : GDS08/IPI21 – ASU 2026 + Co-admin update
Date of local revision : 12 November 2025

Total Colours & Varnishes: 7			
BLACK		124	
165		356	
032		VARNISH	
VARNISH (MATT)			

200 mm Measuring Bar

CARTON FLUARIX TETRA SH 2026

DISETUJUI OLEH BPOM: 04/02/26

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