Description / Id. No. : PI-PIL VAXIGRIP TETRA SH 2025 -1 / XXXXXX		Film Code : KSF/XXXXXX	Printing Colour
Country : Indonesia Version No. : 1 Date : 13.03.2025 Material : HVS 60 g/m² Pharmacode : XXXXX Prepared by : Nuri Hidayati	Min. point size of text : 5 pt Type of text : Noto Sans Family Dimensions : 192 x 400 mm Type of prefold : 2 x Vertical - 3 x Horizontal Dimension after folded : 24 mm x 100 mm (± 2 mm)		Pantone Black Technical Information outline

For Pharmacode

Vaxigrip Tetra® SH

Quadrivalent influenza vaccine
(split virion, inactivated)
Suspension for injection in pre-filled syringe

sanofi

QUALITATIVE AND QUANTITATIVE COMPOSITION
Influenza virus (inactivated, split) 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/Michigan/01/2021, wild type)
..... 15 micrograms HA**
B/Phuket/3073/2013 - like virus (B/Phuket/3073/2013, wild type)
..... 15 micrograms HA**
For one 0.5 mL dose
* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin

This vaccine complies with the WHO recommendations (Southern Hemisphere) for the 2025 season.
For the full list of excipients, see section List of excipients
VaxigripTetra SH may contain traces of eggs, such as ovalbumin, and of neomycin, formaldehyde and octoxinol-9, which are used during the manufacturing process (see section Contraindications).

PHARMACEUTICAL FORM
Suspension for injection in pre-filled syringe.
The vaccine, after shaking gently, is a colourless opalescent liquid.

CLINICAL PARTICULARS
Therapeutic indications
VaxigripTetra SH is indicated for the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine for:
- active immunisation of adults, including pregnant women, and children from 6 months of age.
- passive protection of infant(s) from birth to less than 6 months of age following vaccination of pregnant women (see Sections posology and method of administration; Special warnings and precautions for use; Fertility, pregnancy and lactation and Pharmacodynamic properties – clinical trials).

The use of VaxigripTetra SH should be based on official recommendations.

Posology and method of administration
Posology
Based on clinical experience with the trivalent vaccine, annual revaccination with influenza vaccine is recommended given the duration of immunity provided by the vaccine and because circulating strains of influenza virus might change from year to year.
Adults: one dose of 0.5 mL.
Paediatric population
- Children from 6 months to 17 years of age: one dose of 0.5 mL. For children less than 9 years of age who have not previously been vaccinated, a second dose of 0.5 mL should be given after an interval of at least 4 weeks.
- Infants younger than 6 months of age: No data are available regarding the safety and efficacy of VaxigripTetra SH administration (active immunisation) in infants younger than 6 months of age.

Regarding passive protection, one 0.5 mL dose given to pregnant women may protect infants from birth to less than 6 months of age; however not all these infants will be protected (see Section Pharmacodynamic properties – clinical trials).

Method of administration
The vaccine should be given by intramuscular or subcutaneous injection.
The preferred site for intramuscular injection is 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 administering the medicinal product
For instructions on preparation of the medicinal product before administration, see section Special precautions for disposal & other handling.

Contraindications
Hypersensitivity to the active substances, to any of the excipients listed in section List of Excipients or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde and octoxinol-9.
Vaccination should be postponed in case of moderate or severe febrile disease or acute disease.

Special warnings and precautions for use
As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.
VaxigripTetra SH should under no circumstances be administered intravascularly.
As with other vaccines administered intramuscularly, the vaccine should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

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Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent injury from fainting and manage syncopal reactions.
VaxigripTetra SH is intended to provide protection against those strains of influenza virus from which the vaccine is prepared.
As with any vaccine, vaccination with VaxigripTetra SH may not protect all vaccinees.
Regarding passive protection, not all infants younger than 6 months of age born to women vaccinated during pregnancy will be protected (see Section Pharmacodynamic properties – clinical trials).
Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

Interference with serological testing
See section Interaction with other medicinal products and other forms of interaction

Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed with VaxigripTetra SH.
VaxigripTetra SH can be given at the same time as other vaccines, based on clinical experience with Vaxigrip. Separate injection sites and separate needles should be used in case of concomitant administration.
The immunological response may be reduced 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 results could be due to the IgM response by the vaccine.

Fertility, pregnancy and lactation
Pregnancy
Data from four clinical studies conducted with Vaxigrip (trivalent influenza vaccine, TIV) administered to pregnant women during the second and third trimesters (more than 5,000 exposed pregnancies and more than 5,000 live births, followed up to approximately 6 months postpartum) did not indicate any adverse fetal, newborn, infant, or maternal outcomes attributable to the vaccine.

In three of these clinical studies conducted in South Africa and Nepal, there were no significant differences between the Vaxigrip (TIV) and placebo groups with regards to fetal, newborn, infant, or maternal outcomes (including miscarriage, stillbirth, premature birth, low birth weight).

In the fourth study conducted in Mali, there were no significant differences between the Vaxigrip (TIV) and control vaccine (quadrivalent meningococcal conjugate vaccine) groups with regards to prematurity rate, stillbirth rate, or rate of low birth weight/small for gestational age.

Data from a clinical study conducted in Finland with VaxigripTetra SH administered in pregnant women during the second or third trimester (230 exposed pregnancies and 231 live births) did not indicate any adverse fetal or maternal outcomes attributable to the vaccine.

VaxigripTetra SH can be administered in all stages of pregnancy based on the safety data from clinical studies and post-marketing experience. Because of the known adverse consequences of influenza infection in pregnant women, health authorities recommend vaccination of pregnant women.

One animal study with VaxigripTetra SH did not indicate direct or indirect harmful effects with respect to pregnancy, embryo-foetal development or early post-natal development.

Breastfeeding
There are no data on the use of VaxigripTetra SH in breastfeeding women.
Based on experience with inactivated influenza vaccines, VaxigripTetra SH may be used during breastfeeding.

Fertility
There are no fertility data available in Humans. One animal study with VaxigripTetra SH did not indicate harmful effects on female fertility.

Effects on ability to drive and use machines
VaxigripTetra SH has no or negligible influence on the ability to drive and use machines.

Undesirable effects
Summary of the safety profile
The safety of VaxigripTetra SH was assessed in six clinical trials in which 3,040 adults from 18 to 60 years of age, 1,392 elderly over 60 years of age and 429 children from 9 to 17 years of age received one dose of VaxigripTetra SH, 884 children from 3 to 8 years of age received one or two doses of VaxigripTetra SH depending on their influenza vaccination history and 1614 children from 6 to 35 months of age received two doses (0.5 mL) of VaxigripTetra SH.
Most reactions usually occurred within the first 3 days following vaccination, resolved spontaneously within 1 to 3 days after onset. The intensity of these reactions was mild.
The most frequently reported adverse reaction after vaccination, in all populations, including the whole group of children from 6 to 35 months of age, was injection site pain (between 52.8% and 56.5% in children from 3 to 17 years of age and in adults, 26.8% in children from 6 to 35 months of age and 25.8% in elderly). In subpopulation of children less than 24 months of age, irritability (32.3%) was the most frequently reported adverse reaction.
In subpopulation children from 24 to 35 months of age, malaise (26.8%) is the most frequently reported adverse reaction.
The other most frequently reported adverse reactions after vaccination were:
• In adults: headache (27.8%), myalgia (23%) and malaise (19.2%),
• In elderly: headache (15.6%) and myalgia (13.9%),
• In children from 9 to 17 years of age: myalgia (29.1%), headache (24.7%), malaise (20.3%) and injection site swelling (10.7%),
• In children from 3 to 8 years of age: malaise (30.7%), myalgia (28.5%), headache (25.7%), injection site swelling (20.5%), injection site erythema (20.4%), injection site induration (16.4%), shivering (11.2%).
• For all children from 6 to 35 months of age: fever (20.4%) and injection site erythema (17.2%),
• In children less than 24 months of age: appetite lost (28.9%), crying abnormal (27.1%), vomiting (16.1%) and drowsiness (13.9%),
• In children from 24 months to 35 months of age: headache (11.9%) and myalgia (11.6%).
• Adverse reactions were generally less frequent in the elderly than in adults and children.

Tabulated summary of adverse reactions
The data below summarize the frequencies of the adverse reactions that were recorded following vaccination with VaxigripTetra SH during clinical trials and worldwide post-marketing surveillance.
Adverse events are ranked under headings of frequency using the following convention:
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).
Not known (cannot be estimated from available data)

Adults and elderly
The safety profile presented below is based on:
- data from 3,040 adults from 18 to 60 years of age and 1,392 elderly over 60 years of age.
- data from worldwide post-marketing surveillance (*).

ADVERSE REACTIONS	FREQUENCY
Blood and lymphatic system disorders	
Lymphadenopathy[1]	Uncommon
Immune system disorders	
Hypersensitivity[1], allergic reactions such as angioedema[1], dermatitis allergic[1], pruritus generalized[1], urticaria[1], pruritus[2], erythema	Rare
Anaphylactic reactions	Not known*
Nervous system disorders	
Headache	Very common
Dizziness[3]	Uncommon
Paraesthesia, somnolence	Rare
Vascular disorders	
Hot flush[4]	Uncommon
Respiratory, thoracic and mediastinal disorders	
Dyspnoea[1]	Rare
Gastrointestinal disorders	
Diarrhoea, nausea[5]	Uncommon
Skin and subcutaneous tissue disorders	
Hyperhidrosis	Rare
Musculoskeletal and connective tissue disorders	
Myalgia	Very common
Arthralgia[1]	Rare
General disorders and administration site conditions	
Malaise[6] Injection site pain	Very common
Shivering, fever[2] injection site erythema, injection site swelling, injection site induration	Common
Fatigue injection site ecchymosis, injection site pruritus, injection site warmth	Uncommon
Asthenia, flu-like illness, injection site discomfort[1]	Rare

[1] In adults [2] Uncommon in elderly [3] Rare in adults
[4] In elderly [5] Rare in elderly [6] Common in elderly

Paediatric population
The safety profile presented below is based on:
- data from 429 children from 9 to 17 years of age who received one dose of VaxigripTetra SH and from 884 children from 3 to 8 years of age who received one or two doses of VaxigripTetra SH depending on their influenza vaccination history.
- data from worldwide post-marketing surveillance (*).

ADVERSE REACTIONS	FREQUENCY
Blood and lymphatic system disorders	
Thrombocytopaenia[1]	Uncommon
Immune system disorders	
Allergic including anaphylactic reactions	Not known*
Psychiatric disorders	
Moaning[2], restlessness[2]	Uncommon
Nervous system disorders	
Headache	Very common
Dizziness[2]	Uncommon
Gastrointestinal disorders	
Diarrhoea, vomiting[2], upper abdominal pain[2]	Uncommon
Musculoskeletal and connective tissue disorders	
Myalgia	Very common
Arthalgia[2]	Uncommon
General disorders and administration site conditions	
Malaise, shivering[3], injection site pain, injection site swelling, injection site erythema[3], injection site induration[3]	Very common
Fever injection site ecchymosis	Common
Fatigue[2] injection site warmth[2], injection site pruritus[4]	Uncommon

[1] Reported in one child of 3 years of age [2] Reported in children from 3 to 8 years of age
[3] Common in children from 9 to 17 years of age [4] Reported in children from 9 to 17 years of age

The safety profile presented below is based on:
- data from 1,614 children from 6 to 35 months of age who received two doses of VaxigripTetra SH
- data from worldwide post-marketing surveillance (*).

ADVERSE REACTIONS	FREQUENCY
Immune system Disorders	
Hypersensitivity	Uncommon
Allergic reactions such as pruritus generalised, rash papular	Rare
Anaphylactic reactions	Not known*
Nervous system Disorders	
Headache[1]	Very common
Gastrointestinal Disorders	
Vomiting[2]	Very common
Diarrhoea	Uncommon
Musculoskeletal and Connective Tissue Disorders	
Myalgia[3]	Very common
General Disorders and Administration Site Conditions	
Irritability[4], appetite lost[4], crying abnormal[3], malaise[3], fever, drowsiness[5], injection site pain/tenderness, injection site erythema	Very common
Shivering[3], injection site induration, injection site swelling, injection site ecchymosis	Common
influenza like illness injection site rash, injection site pruritus	Rare

[1] Reported in children ≥ 24 months of age [2] Uncommon in children ≥ 24 months of age
[3] Rare in children < 24 months of age [4] Rare in children ≥ 24 months of age
[5] Reported in children < 24 months of age

In children from 6 months to 8 years of age, the safety profile of VaxigripTetra SH was similar after the first and the second injections with a trend of lower incidence of adverse reactions after the second injection compared to the first one in children from 6 to 35 months of age.

Adverse events
The following adverse events were reported following commercial use of Vaxigrip. A causal relationship with VaxigripTetra SH has not been established.
• ***Blood and lymphatic system disorders***
Transient thrombocytopenia[1], lymphadenopathy[1].
• ***Nervous system disorders***
Paraesthesia[1], Guillain-Barré Syndrome (GBS), neuritis, neuralgia, convulsions, encephalomyelitis
• ***Vascular disorders***
Vasculitis, such as Henoch-Schönlein purpura, with transient renal involvement in certain cases.
[1] These adverse events were reported during clinical trials only in some age groups (see Tabulated summary of adverse reactions).

Other special populations
The safety profile of VaxigripTetra SH observed in a limited number of subjects with co-morbidities enrolled in the clinical studies does not differ from the one observed in the overall population. In addition, studies conducted with Vaxigrip in renal transplant patients, and asthmatic patients showed no major differences in terms of safety profile of Vaxigrip in these populations.

Pregnant women
In clinical studies conducted in pregnant women in South Africa and Mali with Vaxigrip (TIV) (see Section Fertility, Pregnancy and Lactation and Section Pharmacodynamic properties – clinical trials), frequencies of local and systemic solicited reactions reported within 7 days following administration of Vaxigrip, were generally consistent with those reported for the adult population during clinical studies conducted with Vaxigrip; In the study conducted in South Africa, local reactions were more frequent in the Vaxigrip group than in the placebo group in both HIV-negative and HIV-positive cohorts.
There were no other significant differences in solicited reactions between Vaxigrip and placebo groups in both cohorts.
In one clinical study conducted in pregnant women in Finland with VaxigripTetra SH (see Sections Fertility, pregnancy and lactation and Pharmacodynamic properties – Immunogenicity of VaxigripTetra SH), frequencies of local and systemic solicited reactions reported within 7 days following administration of VaxigripTetra SH were consistent with those reported for the non-pregnant adult population during clinical studies conducted with VaxigripTetra SH even though higher for some adverse reactions (injection site pain, malaise, shivering, headache, myalgia). When higher frequencies were observed, this increase was also seen with Vaxigrip (TIV), used as comparator, suggesting a clinical study effect in this pregnant women population.

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.
Overdose
Cases of administration of more than the recommended dose (overdose) have been reported with VaxigripTetra SH. When adverse reactions were reported, the information was consistent with the known safety profile of VaxigripTetra SH described in Section Undesirable effects.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic group: influenza vaccine, ATC code: J07BB02.
Mechanism of action
VaxigripTetra SH provides active immunisation against four influenza virus strains (two A subtypes and two B types) contained in the vaccine.
VaxigripTetra SH induces humoral antibodies against the haemagglutinins within 2 to 3 weeks. These antibodies neutralise influenza viruses.
Specific levels of haemagglutination-inhibition (HAI) antibody titre post-vaccination with inactivated influenza virus vaccines have not been correlated with protection from influenza illness but the HAI antibody titres have been used as a measure of vaccine activity. In some human challenge studies, HAI antibody titres of ≥1:40 have been associated with protection from influenza illness in up to 50% of subjects.
Since influenza viruses constantly evolve, the virus strains selected in the vaccine are reviewed annually by the WHO.

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Lembaran Dalam Kemasan: Informasi Untuk Pasien

Vaxigrip Tetra®
Vaksin influenza Kuadrivalen (split virion, tidak aktif)
Suspensi untuk injeksi

sanofi

Obat ini memerlukan pengawasan tambahan. Ini akan memberikan identifikasi yang cepat atas informasi keselamatan yang baru. Anda dapat membantu dengan melaporkan efek samping yang mungkin Anda dapatkan. Lihat bagian akhir dari Bagian 4 tentang bagaimana melaporkan efek samping.

Baca brosur ini secara hati-hati sebelum Anda atau anak Anda divaksinasi karena berisi informasi penting bagi Anda.
• Simpan brosur ini, mungkin Anda perlu membaca brosur ini kembali.
• Jika ada pertanyaan lebih lanjut, tanyakanlah kepada dokter, apoteker atau perawat Anda.
• Obat ini diresepkan untuk Anda atau anak Anda. Jangan diberikan pada orang lain.
• Jika ada efek samping pada Anda atau anak Anda, bicarakanlah pada dokter, apoteker atau perawat. Hal ini termasuk kemungkinan efek samping apapun yang tidak tercantum dalam selebaran ini. Lihat Bagian 4.

Ada apa dalam selebaran ini

1. Apa itu VaxigripTetra SH dan digunakan untuk apa
2. Hal yang perlu Anda ketahui sebelum Anda atau anak Anda menggunakan VaxigripTetra SH
3. Bagaimana cara menggunakan VaxigripTetra SH
4. Efek samping yang mungkin terjadi
5. Bagaimana cara menyimpan VaxigripTetra SH
6. Isi dari kemasan dan informasi lainnya

1. Apa itu VaxigripTetra SH dan digunakan untuk apa
VaxigripTetra SH adalah vaksin influenza inaktif yang dapat diberikan pada dewasa dan anak mulai usia 6 bulan untuk pencegahan terhadap influenza yang disebabkan strain yang terkandung dalam vaksin, terutama pada subjek dengan risiko tinggi terhadap komplikasi terkait influenza.

Setelah seseorang diberikan VaxigripTetra SH, sistem kekebalan tubuh (sistem pertahanan alami tubuh) akan menghasilkan perlindungannya (antibodi) sendiri terhadap penyakit.
Ketika diberikan selama kehamilan, vaksin ini membantu untuk melindungi wanita hamil tetapi juga membantu untuk melindungi bayinya dari lahir hingga usia hampir 6 bulan melalui transmisi perlindungan dari ibu ke bayi selama kehamilan (Lihat juga Bagian 2 dan 3).
Vaksin ini tidak mengandung bahan-bahan yang bisa menyebabkan flu.
Penggunaan VaxigripTetra SH harus berdasarkan rekomendasi resmi.
Flu adalah penyakit yang dapat menyebar dengan cepat dan disebabkan oleh berbagai jenis organisme yang dapat berubah setiap tahun. Karena perubahan potensial dalam sirkulasi organisme ini terjadi setiap tahun, maka vaksinasi dianjurkan untuk memberikan durasi perlindungan setiap tahunnya. Dokter Anda akan merekomendasikan waktu terbaik untuk divaksinasi.
VaxigripTetra SH dimaksudkan untuk melindungi Anda atau anak Anda terhadap empat strain virus yang terkandung dalam vaksin sekitar 2 hingga 3 minggu setelah injeksi. Selain itu, jika Anda atau anak Anda terinfeksi virus flu sebelum atau sesaat setelah vaksinasi, maka penyakit masih bisa berkembang karena masa inkubasi untuk flu adalah beberapa hari. Vaksin tidak akan melindungi Anda atau anak Anda melawan batuk pilek biasa, yang memiliki beberapa gejala mirip dengan flu.

2. Hal yang perlu Anda ketahui sebelum Anda atau anak Anda menggunakan VaxigripTetra SH
Untuk memastikan bahwa VaxigripTetra SH cocok untuk Anda atau anak Anda, penting untuk memberi tahu dokter atau apoteker Anda jika ada satu atau beberapa poin di bawah ini yang terjadi pada Anda atau anak Anda. Jika ada yang tidak Anda mengerti, tanyakanlah pada dokter atau apoteker Anda.

Jangan gunakan VaxigripTetra SH:
- Jika Anda atau anak Anda alergi terhadap:
  • Zat aktif, atau
  • Bahan lain dalam vaksin ini (tercantum dalam Bagian 6), atau
  • Komponen yang mungkin ada dalam jumlah yang sangat kecil seperti telur (ovalbumin, Protein ayam), neomycin, formaldehyde atau octoxinol-9.
- Jika Anda atau anak Anda menderita penyakit dengan suhu tinggi atau sedang atau penyakit yang akut, vaksinasi harus ditunda sampai Anda atau anak Anda membaik.

Peringatan dan pencegahan
Bicarakanlah dengan dokter, apoteker atau perawat Anda sebelum menggunakan VaxigripTetra SH. Beri tahu dokter Anda sebelum vaksinasi jika Anda atau anak Anda memiliki:
- Respon kekebalan tubuh yang buruk (imunodefisiensi atau mengkonsumsi obat yang mempengaruhi sistem kekebalan),
- Masalah pendarahan atau mudah memar.

Dokter Anda akan memutuskan apakah Anda atau anak Anda harus menerima vaksin.
Pingsan dapat terjadi (kebanyakan pada remaja) setelah, atau bahkan sebelum penyuntikan. Oleh karena itu, beri tahu dokter atau perawat jika Anda atau anak Anda pingsan pada suntikan sebelumnya.
Seperti halnya semua vaksin, VaxigripTetra SH mungkin tidak sepenuhnya melindungi semua orang yang divaksinasi.
Tidak semua bayi kurang dari 6 bulan usia yang dilahirkan oleh wanita hamil yang divaksinasi selama kehamilan mungkin dilindungi.
Jika, karena alasan apa pun, Anda atau anak Anda menjalani tes darah dalam beberapa hari setelah vaksinasi flu, harap beri tahu dokter Anda. Ini karena hasil tes darah positif palsu telah ditemukan pada beberapa pasien yang baru saja divaksinasi.

Anak-anak
VaxigripTetra SH tidak direkomendasikan pada anak-anak di bawah usia 6 bulan.

Obat-obat lain dan VaxigripTetra SH
Beri tahu dokter atau apoteker jika Anda atau anak Anda sedang atau baru mengkonsumsi vaksin lain atau obat-obatan lainnya.
- VaxigripTetra SH dapat diberikan bersamaan dengan vaksin lain pada tempat suntikan yang berbeda.
- Terapi imunosupresan, seperti kortikosteroid, obat sitotoksik atau radioterapi dapat menurunkan respon imunologis.

Kehamilan dan menyusui
Jika Anda sedang hamil atau menyusui, merasa Anda mungkin hamil, mintalah saran kepada dokter atau apoteker Anda sebelum menggunakan vaksin ini.
VaxigripTetra SH dapat digunakan dalam semua tahap kehamilan.
VaxigripTetra SH dapat digunakan selama menyusui.
Dokter/apoteker Anda dapat memutuskan apabila Anda perlu menerima VaxigripTetra SH.

Efek dalam kemampuan mengendarai dan mengoperasikan mesin
VaxigripTetra SH tidak memiliki pengaruh yang berarti terhadap kemampuan mengemudi dan mengoperasikan mesin.

VaxigripTetra SH mengandung kalium dan natrium
Obat ini mengandung kurang dari 1 mmol kalium (39 mg) dan natrium (23 mg) per dosis, dengan kata lain 'bebas kalium' dan 'bebas natrium'.

3. Bagaimana menggunakan VaxigripTetra SH
Dosis
Orang dewasa menerima satu dosis 0,5 mL.
Penggunaan pada anak-anak
Anak-anak dari usia 6 bulan hingga 17 tahun menerima satu dosis 0,5 mL.
Jika anak Anda berusia kurang dari 9 tahun dan belum pernah divaksinasi terhadap flu sebelumnya, dosis kedua sebanyak 0,5 mL harus diberikan setelah selang waktu setidaknya 4 minggu.
Jika Anda sedang hamil, dosis 0,5 mL yang diberikan kepada Anda selama kehamilan dapat melindungi bayi Anda dari lahir hingga usia hampir 6 bulan. Tanyakan kepada dokter atau apoteker Anda untuk informasi lebih lanjut.

Bagaimana memberikan VaxigripTetra SH
Dokter atau perawat Anda akan memberikan dosis vaksin yang disarankan sebagai suntikan ke otot atau di bawah kulit.
Jika Anda atau anak Anda menerima VaxigripTetra SH lebih dari yang seharusnya
Dalam beberapa kasus, lebih dari dosis yang dianjurkan telah secara tidak sengaja diberikan. Dalam kasus ini, ketika efek samping dilaporkan, mereka sejalan dengan apa yang dijelaskan setelah pemberian dosis yang dianjurkan (Lihat Bagian 4).
Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan produk ini, tanyakanlah kepada dokter atau apoteker Anda.

4. Efek samping yang mungkin terjadi
Seperti semua obat-obatan, vaksin ini dapat menyebabkan efek samping, meskipun tidak semua orang mendapatkan efek tersebut.

Reaksi alergi
Segera hubungi dokter atau tenaga kesehatan atau periksakan ke Unit Gawat Darurat rumah sakit terdekat jika Anda atau anak Anda mengalami reaksi alergi (jarang dilaporkan dapat mempengaruhi hingga 1 dari 1.000 orang) yang dapat mengancam nyawa.
Gejala mungkin termasuk ruam, gatal, gatal-gatal, kemerahan, kesulitan bernapas, sesak napas, pembengkakan wajah, bibir, tenggorokan, atau lidah, dingin, kulit terasa lembab dan dingin, berdebar-debar, pusing, kelemahan atau pingsan.

Efek samping lain dilaporkan terjadi pada orang dewasa dan lanjut usia
Sangat umum (dapat mempengaruhi lebih dari 1 dari 10 orang):
- Sakit kepala, nyeri otot (mialgia), umumnya merasa tidak enak badan (*malaise*)[1], nyeri di tempat suntikan.

[1] Umum terjadi pada lansia
Umum (dapat mempengaruhi hingga 1 dari 10 orang):
- Demam[2], menggigil, reaksi di tempat suntikan: kemerahan (eritema), pembengkakan, mengeras (indurasi).

[2] Tidak umum terjadi pada lansia
Tidak umum (dapat mempengaruhi hingga 1 dari 100 orang):
- Pusing[3], diare, mual[4], kelelahan, reaksi di tempat suntikan: memar (*ecchymosis*), gatal (pruritus), dan hangat.

[3] Jarang pada dewasa [4] Jarang pada lansia
- *Hot flush*: hanya terlihat pada orang tua.
  • Pembengkakan kelenjar di leher, ketiak atau selangkangan (limfadenopati): hanya terlihat pada orang dewasa.

Jarang (dapat mempengaruhi hingga 1 dari 1.000 orang):
- Anomali dalam persepsi sentuhan, rasa sakit, panas dan dingin (parestesia), kantuk, peningkatan berkeringat (hiperhidrosis), kelelahan dan kelemahan yang tidak biasa (asthenia), penyakit seperti flu.
- Nyeri sendi (*arthralgia*), ketidaknyamanan di tempat suntikan: hanya terlihat pada orang dewasa.

Efek samping lain yang dilaporkan terjadi pada anak-anak usia 3 hingga 17 tahun
Sangat umum (dapat mempengaruhi lebih dari 1 dari 10 orang):
- Sakit kepala, nyeri otot (mialgia), umumnya merasa tidak enak badan (*malaise*), menggigil[5], reaksi di tempat suntikan: nyeri, bengkak, kemerahan (eritema)[5], mengeras (indurasi)[5].

[5] Umum pada anak-anak usia 9 hingga 17 tahun
Umum (dapat mempengaruhi hingga 1 dari 10 orang):
- Demam, memar (*ecchymosis*) di tempat suntikan.

Tidak umum (dapat mempengaruhi hingga 1 dari 100 orang) pada anak-anak usia 3 hingga 8 tahun:
- Pengurangan sementara jumlah elemen darah tertentu yang disebut trombosit; jumlah yang rendah ini dapat menyebabkan memar berlebihan atau pendarahan (trombositopenia transien): hanya terlihat pada satu anak berusia 3 tahun.
- Merintih, gelisah.
- Pusing, diare, muntah, nyeri perut bagian atas, nyeri sendi (*arthralgia*), kelelahan, hangat di tempat suntikan.
- Jarang (dapat mempengaruhi hingga 1 dari 100 orang) pada anak-anak usia 9 sampai 17 tahun:
- Diare, gatal (pruritus) di tempat suntikan.

Efek samping lain yang dilaporkan terjadi pada anak-anak usia 6 hingga 35 bulan
Sangat umum (dapat mempengaruhi hingga 1 dari 10 orang):
- Mumtah[1], nyeri otot (mialgia)[2], mudah marah[3], hilang nafsu makan[3], umumnya merasa tidak enak badan (malaise)[2], demam.

[1] Tidak umum pada anak-anak berusia dari 24 hingga 35 bulan [2] Jarang pada anak-anak berusia kurang dari 24 bulan
[3] Jarang pada anak-anak berusia dari 24 hingga 35 bulan
- Reaksi di tempat suntikan: nyeri/sensitif, kemerahan (eritema).
- Sakit kepala: hanya terlihat pada anak-anak berusia dari 24 bulan.

KSF/XXXXXX

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Description / Id. No. : PI-PIL VAXIGRIP TETRA SH 2025 -1 / XXXXXX	Film Code : KSF/XXXXXX	Printing Colour
Country : Indonesia Version No. : 1 Date : 13.03.2025 Material : HVS 60 g/m² Pharmacode : XXXXX Prepared by : Nuri Hidayati	Min. point size of text : 5 pt Type of text : Noto Sans Family Dimensions : 192 x 400 mm Type of prefold : 2 x Vertical - 3 x Horizontal Dimension after folded : 24 mm x 100 mm (± 2 mm)	Pantone Black Technical Information outline

- Mengantuk, tangisan yang tidak biasa: hanya terlihat pada anak-anak berusia kurang dari 24 bulan.

Umum (dapat mempengaruhi sampai 1 dari 10 orang):
- Menggigil: hanya terlihat pada anak-anak berusia 24 bulan dan lebih tua.
- Reaksi di tempat suntikan: mengeras (indurasi), pembengkakan, memar (*ecchymosis*).

Jarang (dapat mempengaruhi sampai 1 dari 100 orang):
- Diare, hipersensitivitas.

Jarang (dapat mempengaruhi sampai 1 dari 1.000 orang):
- Penyakit seperti flu, reaksi di tempat suntikan: ruam, pruritus (gatal).

Pada anak-anak dari usia 6 bulan hingga 8 tahun yang menerima 2 dosis, mendapat efek samping serupa setelah dosis pertama dan kedua. Efek samping yang lebih sedikit dapat terjadi setelah dosis kedua pada anak-anak dari usia 6 sampai 35 bulan.

Efek samping umumnya terjadi dalam 3 hari pertama setelah vaksinasi dan hilang dengan sendirinya dalam 1 hingga 3 hari setelah mulai terjadi efek samping. Intensitas efek samping yang diamati ringan.
Efek samping umumnya lebih jarang terjadi pada lansia dibandingkan pada orang dewasa dan anak-anak.
Efek samping berikut telah dilaporkan setelah pemberian Vaxigrip. Efek samping ini dapat terjadi dengan VaxigripTetra SH:
- Nyeri terletak pada jalur saraf (neuralgia), kejang (kejang), gangguan neurologis yang dapat menyebabkan kaku leher, kebingungan, mati rasa, nyeri dan kelemahan anggota badan, kehilangan keseimbangan, kehilangan refleks, kelumpuhan sebagian atau seluruh tubuh (*encephalomyelitis*, neuritis, sindrom *Guillain-Barré*).
- Peradangan pembuluh darah (vasculitis) yang dapat menyebabkan ruam kulit dan dalam kasus yang sangat jarang terjadi pada masalah ginjal sementara.
- Trombositopenia transien, limfadenopati, parestesia dalam kelompok usia selain yang dijelaskan di atas untuk efek samping ini.

Pelaporan efek samping
Jika Anda atau anak Anda mendapatkan efek samping, bicarakanlah dengan dokter, apoteker atau perawat Anda. Termasuk kemungkinan efek samping yang tidak tercantum dalam brosur ini.
Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.

5. Bagaimana cara menyimpan VaxigripTetra SH
Jauhkan vaksin ini dari pandangan dan jangkauan anak-anak.
Jangan gunakan vaksin ini setelah tanggal kedaluwarsa yang tercantum pada label dan karton setelah EXP. Tanggal kedaluwarsa mengacu pada hari terakhir bulan itu.
Simpan dalam lemari pendingin (2°C – 8°C). Jangan dibekukan. Simpan alat suntik di karton luar, untuk melindungi dari cahaya.
Jangan membuang obat apa pun melalui air limbah atau limbah rumah tangga. Tanyakanlah pada apoteker Anda bagaimana membuang obat-obatan yang tidak lagi Anda gunakan. Langkah-langkah ini akan membantu melindungi lingkungan.

6. Isi dari kemasan dan informasi lainnya
Apa isi dari VaxigripTetra SH
- Zat aktifnya adalah: Virus influenza (tidak aktif, terbagi) dari organisme berikut *:
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/Michigan/01/2021, wild type)
.....15 mikrogram HA**
B/Phuket/3073/2013 - like virus (B/Phuket/3073/2013, wild type)
.....15 mikrogram HA**
Untuk satu dosis 0,5 mL

* diperbanyak dalam telur ayam yang dibuahi dari unggas ayam yang sehat
** haemagglutinin

Vaksin ini sesuai dengan rekomendasi WHO (World Health Organization/Organisasi Kesehatan Dunia) (Belahan Bumi Selatan) untuk musim 2025.
- Bahan lain adalah: larutan penyangga yang mengandung natrium klorida, kalium klorida, disodium fosfat dihidrat, kalium dihidrogen fosfat, dan air untuk injeksi.

Beberapa komponen seperti telur (ovalbumin, protein ayam), neomisin, formaldehida atau oktoksinol-9 mungkin ada dalam jumlah yang sangat kecil (lihat Bagian 2).

Seperti apa VaxigripTetra SH dan isi kemasannya
Vaksin, setelah dikocok dengan perlahan, adalah cairan opalescent tak berwarna.
Bentuk sediaan adalah suspensi untuk injeksi dengan kemasan sebagai berikut :

HARUS DENGAN RESEP DOKTER

Kemasan :
Dus, 1 *pre-filled syringe* @ 0,5 mL
No. Registrasi: DKI2059703643A1

Diproduksi oleh :
Sanofi Winthrop Industrie, Val-de-Reuil - France

Didaftarkan oleh :
PT Kalventis Sinergi Farma, Jakarta - Indonesia

Based on BPOM Approval dated 09 January 2024

Annual revaccination with VaxigripTetra SH has not been studied. However, based on clinical experience with the trivalent vaccine, annual influenza vaccination is recommended given the duration of immunity provided by the vaccine and because circulating strains of influenza virus change from year to year.

Efficacy of VaxigripTetra SH
Paediatric population
• Children from 6 to 35 months of age (active immunisation):
A randomized placebo controlled study was conducted in 4 regions (Africa, Asia, Latina America and Europe) over 4 influenza seasons, in more than 5,400 children from 6 to 35 months of age who received two doses (0.5 mL) of VaxigripTetra SH (N=2,722), or placebo (N=2,717) 28 days apart to assess VaxigripTetra SH efficacy for the prevention of laboratory-confirmed influenza illness caused by any strain A and/or B and caused by vaccine similar strains (as determined by sequencing).

Laboratory-confirmed influenza illness was defined as influenza like-illness (ILI) [occurrence of fever ≥ 38°C (that lasts at least 24 hours) concurrently with at least one of the following symptoms: cough, nasal congestion, rhinorrhoea, pharyngitis, otitis, vomiting, or diarrhoea], laboratory-confirmed by reverse transcriptase polymerase chain reaction (RT-PCR) and/or viral culture.

Table 1: Influenza Attack Rates and VaxigripTetra SH Efficacy against laboratory-confirmed influenza illness in children from 6 to 35 months of age

	Vaxigrip Tetra SH (N=2,584)		Placebo (N=2,591)		Efficacy
	n	Influenza attack rate (%)	n	Influenza attack rate (%)	% (2-sided 95% CI)
Laboratory-confirmed influenza illness caused by:					
- Any influenza A or B type	122	4.72	255	9.84	52.03 (40.24; 61.66)
- Viral strains similar to those contained in the vaccine	26	1.01	85	3.28	69.33 (51.93; 81.03)

N: number of children analysed (full set)
n: number of subjects fulfilling the item listed
CI: Confidence Interval

In addition, a predefined complementary analysis showed VaxigripTetra SH prevented 56.6% (95% CI: 37.0; 70.5) of severe laboratory-confirmed influenza illnesses due to any strain, and 71.7% (95% CI: 43.7; 86.9) of severe laboratory-confirmed influenza illnesses due to vaccine similar strains.
Furthermore, subjects receiving VaxigripTetra SH were 59.2% (95% CI: 44.4; 70.4) less likely to experience a medically attended influenza illness than subjects receiving placebo.

Severe laboratory-confirmed influenza illnesses were defined as ILI laboratory-confirmed by RT- PCR and/or viral culture with at least one of the following items:
- fever > 39.5°C for subjects aged < 24 months or ≥ 39.0°C for subjects aged ≥ 24 months,
- and/or at least one significant ILI symptom which prevents daily activity (cough, nasal congestion, rhinorrhoea, pharyngitis, otitis, vomiting, diarrhoea),
- and/or one of the following events: acute otitis media, acute lower respiratory infection (pneumonia, bronchiolitis, bronchitis, croup), inpatient hospitalization.

• Children from 3 to 8 years of age (active immunisation):
Based on immune responses observed in children from 3 to 8 years of age, the efficacy of VaxigripTetra SH in this population is expected to be at least similar to the efficacy observed in children from 6 to 35 months (see "Children from 6 to 35 months of age" above and "Immunogenicity of VaxigripTetra SH" below).

• Pregnant women
There are no clinical efficacy data describing use of VaxigripTetra SH in pregnant women. However,data are available on Vaxigrip (TIV) and cited below, and can be extrapolated to VaxigripTetra SH.

In the randomised, controlled, phase IV, clinical studies conducted in Mali, Nepal, and South Africa, approximately 5,000 pregnant women received Vaxigrip (TIV) and approximately 5,000 pregnant women received placebo or control vaccine (quadrivalent meningococcal conjugate vaccine) during the second or third trimester of pregnancy. Vaccine efficacy against laboratory-confirmed influenza in pregnant women was evaluated as a secondary endpoint in all three studies.

The studies conducted in Mali and South Africa demonstrated the efficacy of Vaxigrip for the prevention of influenza in pregnant women (during pregnancy and for approximately 6 months post- delivery), following vaccination during these trimesters of pregnancy.
In the study conducted in Nepal, the efficacy of Vaxigrip (TIV) for the prevention of influenza in pregnant women following vaccination during these trimesters of pregnancy was not demonstrated.

Table 2: Influenza Attack Rates and Vaxigrip Efficacy against laboratory-confirmed influenza Illness in pregnant women

	Influenza Attack Rate (Any influenza A or B type) % (n/N)		Vaxigrip Efficacy % (95% CI)
	Vaxigrip	Control*	
Mali	0.5 (11/2,108)	1.9 (40/2,085)	70.3 (42.2; 85.8)
	Vaxigrip	Placebo	
South Africa	1.8 (19/1,062)	3.6 (38/1,054)	50.4 (14.5; 71.2)

*Meningococcal vaccine
N: Number of pregnant women included in analysis
n: number of subjects with laboratory confirmed infuenza illness
CI: Confidence Interval

•Infants younger than 6 months of age born to vaccinated pregnant women (passive protection)
Infants younger than 6 months of age are at high risk of influenza, resulting in high rates of hospitalization; however, influenza vaccines are not indicated for use in this age group.
There are no clinical efficacy data in infants born to women vaccinated with VaxigripTetra SH during pregnancy; however, efficacy in infants younger than 6 months of age whose mothers received a single 0.5 mL dose of Vaxigrip (TIV) during the second or third trimester has been demonstrated in clinical trials in Nepal, Mali and South Africa and can be extrapolated to VaxigripTetra SH. Efficacy of Vaxigrip (TIV) in infants younger than 6 months of age whose mothers were vaccinated during the first trimester has not been studied in these trials. Nevertheless, influenza vaccination during the first trimester should not be postponed (see Section Fertility, pregnancy and lactation).

Table 3: Influenza Attack Rates and Vaxigrip Efficacy against Laboratory- confirmed influenza illness in infants born to women vaccinated during pregnancy

	Influenza Attack Rate (Any influenza A or B type) % (n/N)		Vaxigrip Efficacy % (95% CI)
	Vaxigrip	Control*	
Mali	2.4 (45/1,866)	3.8 (71/1,869)	37.3 (7.6; 57.8)
	Vaxigrip	Placebo	
Nepal	4.1 (74/1,820)	5.8	30.0 (5; 48)
South Africa	1.9 (19/1,026)	(105/1,826)	48.8 (11.6; 70.4)

* Meningococcal vaccine
N: Number of infants included in the analysis
n: number of subjects with laboratory-confirmed influenza illness
CI: Confidence Interval

The efficacy data indicate a waning of protection in infants born to vaccinated mothers over time after birth.

In the trial conducted in South Africa, vaccine efficacy was highest among infants 8 weeks of age or younger (85.8% [95% CI, 38.3 to 98.4]) and decreased over time; vaccine efficacy was 25.5% (95% CI, -67.9 to 67.8) for infants >8 to 16 weeks of age and 30.4% (95% CI, -154.9 to 82.6) for infants >16 to 24 weeks of age.

In the trial conducted in Mali, there is also a trend of higher efficacy of the trivalent inactivated influenza vaccine in infants during the first 4 months after birth (70.2% [95% CI, 35.7 to 87.6]), with lower efficacy within the fifth month of surveillance (60.7% [95% CI, 33.8 to 77.5]) and a marked fall within the sixth month (37.3% [95% CI, 7.6 to 57.8]).

The prevention of influenza can only be expected if the infants are exposed to the strains included in the vaccine administered to the mother.

Immunogenicity of VaxigripTetra SH
Clinical studies performed in adults from 18 to 60 years of age, in elderly over 60 years of age, in children from 3 to 8 years of age and from 6 to 35 months assessed VaxigripTetra SH immune response for HAI Geometric mean antibody titer (GMT) at Day 21 (for adults) and at Day 28 (for children), HAI seroconversion rate (4-fold rise in reciprocal titer or change from undetectable [<10] to a reciprocal titer of ≥40), and HAI GMTR (post-/pre-vaccination titers).
One clinical study performed in adults from 18 to 60 years of age and in children from 9 to 17 years of age described the immune response of VaxigripTetra SH for HAI antibody GMT at Day 21. Another clinical study performed in children from 9 to 17 years of age described the immune response of VaxigripTetra SH.
One clinical study performed in pregnant women described the immune response of VaxigripTetra SH versus Vaxigrip (TIV) for HAI GMT at Day 21, HAI seroconversion rate, and HAI GMTR after one dose administered during the second or third trimester of pregnancy.
In this study, the transplacental transfer was evaluated using HAI GMTs of maternal blood, of cord blood and of ratio cord blood/maternal blood, at delivery
VaxigripTetra SH induced a significant immune response against the 4 influenza strains contained in the vaccine.

Adults and elderly
A total of 832 adults from 18 to 60 years of age and 831 elderly over 60 years of age were assessed in terms of immune response after one dose of VaxigripTetra SH.
Immunogenicity results are presented in the tables below:

Table 4: Immunogenicity results in adults from 18 to 60 years of age and in elderly over 60 years of age

Antigen strain	18 to 60 years of age N=832	Over 60 years of age N=831
	GMT (95% CI)	
A (H1N1) (a)(b)	608 (563; 657)	219 (199; 241)
A (H3N2)	498 (459; 541)	359 (329; 391)
B (Victoria)	708 (661; 760)	287 (265; 311)
B (Yamagata)	1715 (1607: 1830)	655 (611; 701)
	SC % (95% CI)(c)	
A (H1N1) (a)(b)	64.1 (60.7; 67.4)	45.6 (42.1; 49.0)
A (H3N2)	66.2 (62.9; 69.4)	47.5 (44.1; 51.0)
B (Victoria)	70.9 (67.7; 74.0)	45.2 (41.8; 48.7)
B (Yamagata)	63.7 (60.3; 67.0)	42.7 (39.3; 46.2)
	GMTR (95% CI)(d)	
A (H1N1) (a)(b)	9.77 (8.69; 11.0)	4.94 (4.46; 5.47)
A (H3N2)	10.3 (9.15; 11.5)	5.60 (5.02; 6.24)
B (Victoria)	11.6 (10.4; 12.9)	4.61 (4.18; 5.09)
B (Yamagata)	7.35 (6.66; 8.12)	4.11 (3.73; 4.52)

N= number of subjects with available data for the considered endpoint
GMT: Geometric Mean Titer; CI: Confidence Interval;
(a) N=833 for 18-60 years of age group
(b) N=832 for over 60 years of age group
(c) SC: Seroconversion or significant increase: for subjects with a pre-vaccination titer <10 (1/dil), proportion of subjects with a post-vaccination titer ≥ 40 (1/dil) and for subjects with a pre-vaccination titer ≥10 (1/dil), proportion of subjects with a ≥four-fold increase from pre- to post-vaccination titer
(d) GMTR: Geometric mean of individual titer ratios (post-/pre-vaccination titers)

Pregnant women and transplacental transfer
In a randomised, controlled clinical study conducted in Finland, a total of 230 pregnant women received VaxigripTetra SH and 116 pregnant women received Vaxigrip (TIV) during the second or third trimester of pregnancy (from 20 to 32 weeks of pregnancy).

Immunogenicity results by HAI method, in pregnant women 21 days after vaccination with VaxigripTetra SH or Vaxigrip (TIV) are presented in table 5.

Immunogenicity descriptive assessment by HAI method, at delivery, in blood sample of mother (BL03M), in cord blood sample (BL03B) and of the transplacental transfer (BL03B/BL03M) are presented in table 5.

At delivery, the level of antibodies in the cord sample compared to the mother sample was almost doubled for the A/H1N1 strain and increased between 1.5 and 1.7 times for the A/H3N2, B/Brisbane, and B/Phuket strains, supporting that there is transplacental antibody transfer from mother to the newborn, following vaccination of women with VaxigripTetra SH or Vaxigrip (TIV) during the second or third trimester of pregnancy.

These data are consistent with the passive protection demonstrated in infants from birth to approximately 6 months of age following vaccination of women during the second or third trimester of pregnancy with Vaxigrip (TIV) in studies conducted in Mali, Nepal, and South Africa.

Table 5 Immunogenicity results by HAI method in pregnant women, 21 days post-vaccination with Vaxigrip Tetra SH and at delivery

Antigen strain	Pregnant woman	At Delivery N* =178
	GMT (95% CI)	**BL03M (c) GMT (95% CI)**
A (H1N1)*	525 (466; 592)	304 (265 ; 349)
A (H3N2) *	341 (286; 407)	178 (146 ; 218)
B1 (Victoria) *	568 (496; 651)	290 (247 ; 341)
B2 (Yamagata) *,	993 (870; 1134)	547 (463 ; 646)
	≥4-fold-rise n (%) (a)	**BL03B (d) GMT (95% CI)**
A (H1N1) *	38.0 (31.5; 44.8)	576 (492 ; 675)
A (H3N2) *	59.3 (52.4; 65.9)	305 (246 ; 379)
B1 (Victoria) *	61.1 (54.3; 67.7)	444 (372 ; 530)
B2 (Yamagata) *	59.7 (52.9; 66.3)	921 (772 ; 1099)
	GMTR (95% CI)(b)	**Transplacental transfer: BL03B/BL03M(e) GMT (95% CI)**
A (H1N1) *	3.81 (3.11; 4.66)	1.89 (1.72 ; 2.08)
A (H3N2) *	8.63 (6.85; 10.9)	1.71 (1.56 ; 1.87)
B1 (Victoria) *	8.48 (6.81; 10.6)	1.53 (1.37 ; 1.71)
B2 (Yamagata) *	6.26 (5.12; 7.65)	1.69 (1.54 ; 1.85)

N: number of subjects with available data for the considered endpoint
N*: number of subjects with available data for the considered endpoint: women who received QIV or TIV, delivered at least 2 weeks after injection and with available cord blood and mother blood at the time of delivery

*A/H1N1: A/Michigan/45/2015 (H1N1) pdm09-like virus; A/H3N2: A/Hong Kong/4801/2014 (H3N2)-like virus;
B1: B/Brisbane/60/2008-like virus (B/Victoria lineage):
B2: B/Phuket/3073/2013-like virus (B/Yamagata lineage)

GMT: Geometric Mean Titer; CI: Confidence Interval

(a) SC: Seroconversion or significant increase: for subjects with a pre-vaccination titer <10 (1/dil), proportion of subjects with a post-vaccination titer ≥40 (1/dil) and for subjects with a pre-vaccination titer ≥10 (1/dil), proportion of subjects with a ≥four-fold increase from pre- to post-vaccination titer
(b) GMTR: Geometric mean of individual titer ratios (post-/pre-vaccination titers)
(c) BL03M: Blood sample of mother at delivery
(d) BL03B: Cord blood sample at delivery
(e) If a mother has X babies, her titers values is counted X times

Paediatric population
• Children from 9 to 17 years of age:
In a total of 429 children from 9 to 17 years of age who received one dose of VaxigripTetra SH, the immune response against the 4 strains contained in the vaccine was similar to the immune response induced in adults from 18 to 60 years of age.

• Children from 6 months to 8 years of age:
A total of 863 children from 3 to 8 years of age received either one or two doses of VaxigripTetra SH depending on their previous influenza vaccination history.
Children who received a one- or two-dose schedule of VaxigripTetra SH presented a similar immune response following the last dose of each schedule.
In addition to the VaxigripTetra SH efficacy, the immunogenicity of two 0.5 mL doses of VaxigripTetra SH was assessed 28 days after the last injection of VaxigripTetra SH by HAI method in 341 children from 6 to 35 months of age.

Immunogenicity results are presented in the table below:

Table 6: Immunogenicity results in children from 6 months to 8 years of age

Antigen strain	6-35 months of age N=341	3-8 years of age N=863
	GMT (95% CI)	
A (H1N1)	641 (547; 752)	971 (896; 1052)
A (H3N2)	1071 (925; 1241)	1568 (1451; 1695)
B (Victoria)	623 (550; 706)	1050 (956; 1154)
B (Yamagata)	1010 (885; 1153)	1173 (1078; 1276)
	SC % (95% CI)(b)	
A (H1N1)	90.3 (86.7; 93.2)	65.7 (62.4; 68.9)
A (H3N2)	90.3 (86.7; 93.2)	64.8 (61.5; 68.0)
B (Victoria)	98.8 (97.0; 99.7)	84.8 (82.3; 87.2)
B (Yamagata) (a)	96.8 (94.3; 98.4)	88.5 (86.2; 90.6)
	GMTR (95% CI)(c)	
A (H1N1)	36.6 (30.8; 43.6)	6.86 (6.24; 7.53)
A (H3N2)	42.6 (35.1; 51.7)	7.49 (6.72; 8.35)
B (Victoria)	100 (88.9; 114)	17.1 (15.5; 18.8)
B (Yamagata) (a)	**93.9 (79.5; 111)**	**25.3 (22.8; 28.2)**

N=number of subjects with available data for the considered endpoint;
GMT: Geometric Mean Titer;
CI: Confidence Interval;
(a) N=862 for 3-8 years of age group
(b) SC: seroconversion or significant increase: for subjects with a pre-vaccination titer <10 (1/dil), proportion of subjects with a post-vaccination titer ≥40 (1/dil) and for subjects with a pre-vaccination titer ≥10 (1/dil), proportion of subjects with a ≥four-fold increase from pre- to post- vaccination titer
(c) GMTR: Geometric mean of individual titer ratios (post-/pre-vaccination titers)

These immunogenicity data provide supportive information in addition to vaccine efficacy data available in this population (see Efficacy of VaxigripTetra SH).

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
Buffer Solution:
• Sodium chloride
• Potassium chloride
• Disodium phosphate dihydrate
• Potassium dihydrogen phosphate
• Water for injections

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

Special precautions for storage
Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

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.
The vaccine should not be used if foreign particles are present in the suspension.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Packaging Presentation
Box, 1 pre-filled syringe @ 0.5 mL
Reg No. DKI2059703643A1

HARUS DENGAN RESEP DOKTER

Manufactured by:
Sanofi Winthrop Industrie, Val-de-Reuil - France

Registered by
PT Kalventis Sinergi Farma, Jakarta - Indonesia

Based on BPOM Approval dated 09 January 2024

REVISION HISTORY

Date	Item Code (Version Number)	Description Of Change
13/03/2025	KSF/XXXXXX (Versi 1)	• New launch (Alfa Project Vaccines for BPOM submission) • CC-1770 (Change labeling of VaxigripTetraSH due to change DP's manufacturer name and removal of releaser)