VAXIGRIP TIV NH

TRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)
Suspension for injection in prefilled syringe

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/Darwin/9/2021 (H3N2)-like virus (A/Darwin/9/2021, IVR-228) ..... 15 micrograms HA**
- B/Austria/1359417/2021-like virus (B/Michigan/01/2021, 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 (Northern Hemisphere) and EU decision for the 202X/202X season.
For the full list of excipients, see section List of excipients.
Vaxigrip TIV NH 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

Vaxigrip TIV NH is indicated for the prevention of influenza disease caused by the two influenza A virus subtypes and the influenza B virus type contained in the vaccine for:

- active immunisation of adults, including pregnant women, and children from 6 months of age and older,
- passive protection of infant(s) from birth to less than 6 months of age following vaccination of pregnant women (see Sections Special warnings and precautions for use; Fertility, pregnancy and lactation; Pharmacodynamic properties).

The use of Vaxigrip TIV NH should be based on official recommendations on vaccination against influenza.

Posology and method of administration

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.

Posology

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 less than 6 months of age: the safety and efficacy of Vaxigrip TIV NH administration (active immunisation) have not been established. No data are available.
  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 preferred route of administration for this vaccine is intramuscular although it can also be given subcutaneously.
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 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.

Special warnings and precautions for use
Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Hypersensitivity
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.

Concurrent illness
Vaccination should be postponed in patients with acute febrile illness until the fever is resolved.

Precautions for use
Vaxigrip TIV NH should under no circumstances be administered intravascularly.

Thrombocytopenia and coagulation disorders
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.

Syncope
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.

Protection
Vaxigrip TIV NH is intended to provide protection against those strains of influenza virus from which the vaccine is prepared.

As with any vaccine, vaccination with Vaxigrip TIV NH may not protect all vaccinees.

Regarding passive protection, not all infants less than 6 months of age born to women vaccinated during pregnancy will be protected (see Section Pharmacodynamic properties – clinical trials).

Immunodeficiency
Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

Potassium and sodium content
Vaxigrip TIV NH contains less than 1 mmol potassium (39 mg) and sodium (23 mg) per dose, i.e. essentially 'potassium-free' and 'sodium-free'.

Interaction with other medicinal products and other forms of interaction
Vaxigrip TIV NH could be given at the same time as other vaccines if needed. Separate injection sites and separate syringes should be used in case of concomitant administration.
Data showing that Vaxigrip TIV NH can be administered concomitantly with other vaccines are available for the following vaccines: a pneumococcal polysaccharide vaccine, a tetanus, diphtheria, pertussis, polio vaccine (Tdap-IPV, Repevax), and a zoster vaccine. If Vaxigrip TIV NH is given at the same time as other vaccines, separate injection sites and separate syringes should be used.
The immunological response may be reduced if the patient is undergoing immunosuppressant treatment.

Fertility, pregnancy and lactation
Pregnancy
Pregnant women are at high risk of influenza complications, including premature labour and delivery, hospitalization, and death: pregnant women should receive an influenza vaccine.

Vaxigrip TIV NH can be used in all stages of pregnancy.

Larger datasets on safety of inactivated influenza vaccines are available for the second and third trimesters than for with the first trimester. Data from worldwide use of inactivated influenza vaccines, including Vaxigrip TIV NH and Vaxigrip Tetra NH (quadrivalent inactivated influenza vaccine), do not indicate any adverse foetal and maternal outcomes attributable to the vaccine.

This is consistent with results observed in one clinical study where Vaxigrip TIV NH and Vaxigrip Tetra NH were administered in pregnant women during the second or third trimester (116 exposed pregnancies and 119 live births for Vaxigrip TIV NH, 230 exposed pregnancies and 231 live births for Vaxigrip Tetra NH).

Data from four clinical studies with Vaxigrip TIV NH administered in pregnant women during the second or third trimester (more than 5,000 exposed pregnancies and more than 5,000 live births followed up to approximately 6 months post-partum) did not indicate any adverse foetal, newborn, infant and maternal outcomes attributable to the vaccine.

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

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

For additional information, see Sections Undesirable effects and Pharmacodynamic properties.

Results of one animal reproductive study conducted with Vaxigrip Tetra NH (60 µg of total amount HA/dose) can be extrapolated to Vaxigrip TIV NH (45 µg of total amount HA /dose): this study did not indicate direct or indirect harmful effects with respect to pregnancy, embryo-foetal development or early post-natal development.

Breast-feeding

There are no data on the effect of the vaccine in breastfed newborns/infants of women vaccinated with Vaxigrip TIV NH during breastfeeding period. Based on inactivated influenza vaccines experience, Vaxigrip TIV NH may be used during breastfeeding.

Fertility
No fertility data are available in Humans. One animal study with Vaxigrip Tetra NH did not indicate harmful effects on female fertility.

Effects on ability to drive and use machines
Vaxigrip TIV NH has no or negligible influence on the ability to drive and use machines.

Undesirable effects
Summary of the safety profile
The safety profile of Vaxigrip TIV NH is based on data from 46 clinical studies in which approximately 17,900 participants from 6 months of age received Vaxigrip TIV NH or Vaxigrip Tetra NH, and on the post-marketing surveillance.

Most of adverse reactions usually occurred within the first 3 days after vaccination and resolved spontaneously within 1 to 3 days after onset. The intensity of most these reactions was mild to moderate.

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.

Tabulated list of adverse reactions
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);
Not known (cannot be estimated from available data)

Adult and elderly
The safety profile is based on data:
- from clinical studies in more than 8,000 adults (5,064 for Vaxigrip TIV NH, 3,040 for Vaxigrip Tetra NH) and more than 5,800 elderly over 60 years of age (4,468 for Vaxigrip TIV NH, 1,392 for Vaxigrip Tetra NH),
- from worldwide post-marketing surveillance in the overall population.

In adults, the most frequently reported adverse reactions after vaccination were injection site pain (52.8%), headache (27.8%), myalgia (23.0%), malaise (19.2%).
In the elderly, the most frequently reported adverse reactions after vaccination were injection site pain (25.8%), headache (15.6%), myalgia (13.9%).

Table 1: Adverse reactions reported in adults and elderly

System Organ Class (SOC)/Adverse Reactions	Frequency
Blood and Lymphatic System Disorders	
Lymphadenopathy [(1)]	Uncommon
Transient thrombocytopenia	Not known*
Immune System Disorders	
Allergic reactions such as hypersensitivity[(2)], dermatitis atopic[(2)], urticaria[(2, 3)], oropharyngeal pain, asthma[(1)], rhinitis allergic[(2)], rhinorrhea[(1)], conjunctivitis allergic[(2)], pruritus[(4)], hot flush[(5)]	Uncommon

System Organ Class (SOC)/Adverse Reactions	Frequency
Allergic reactions such as angioedema[2, 3], swelling face, erythema, rash, flushing[5], oral mucosal eruption [5], paraesthesia oral[5], throat irritation, dyspnea[2, 3], sneezing, nasal obstruction[2], upper respiratory tract congestion[2], ocular hyperaemia[2], dermatitis allergic[2], pruritus generalised[2]	Rare
Allergic reactions such as rash erythematous, anaphylactic reaction, shock	Not known*
Metabolism and Nutrition Disorders	
Decreased appetite	Rare
Nervous System Disorders	
Headache	Very common
Dizziness[4], somnolence[4]	Uncommon
Hypoaesthesia[2], paresthesia	Rare
Neuralgia, convulsions, encephalomyelitis, neuritis, Guillain Barré Syndrome	Not known*
Vascular disorders	
Vasculitis such as Henoch-Schonlein purpura, with transient renal involvement in certain cases	Not known*
Gastrointestinal Disorders	
Diarrhea, nausea	Uncommon
Abdominal pain[2], vomiting	Rare
Skin and Subcutaneous System Disorders	
Hyperhidrosis[1]	Uncommon
Musculoskeletal and Connective Tissue Disorders	
Myalgia	Very common
Arthralgia[1]	Uncommon
General Disorders and Administration Site Conditions	
Injection site pain, malaise[6]	Very common
Fever[7], shivering, injection site erythema, injection site induration, injection site swelling	Common
Asthenia[1], fatigue, injection site ecchymosis, injection site pruritus, injection site warmth, injection site discomfort,	Uncommon
Flu-like symptoms, injection site exfoliation[5], injection site hypersensitivity[2]	Rare

[1] Rare in elderly
[2] Reported during clinical trials in adults
[3] Not known in elderly
[4] Rare in adults
[5] Reported during clinical trials in elderly
[6] Common in elderly
[7] Uncommon in elderly
(*) Adverse reactions reported post-marketing after use of Vaxigrip TIV NH or Vaxigrip Tetra NH

Paediatric population

The safety profile is based on data:

- from clinical studies in 1 247 children from 3 to 8 years of age (363 for Vaxigrip TIV NH, 884 for Vaxigrip Tetra NH) and in 725 children/adolescents from 9 to 17 years of age (296 for Vaxigrip TIV NH, 429 for Vaxigrip Tetra NH),
- from one clinical study in 1 981 children from 6 to 35 months of age (367 for Vaxigrip TIV NH, 1 614 for Vaxigrip Tetra NH),
- from worldwide post-marketing surveillance in the overall population.

Depending on immunization history, children from 6 months to 8 years of age received one or two doses of Vaxigrip TIV NH or Vaxigrip Tetra NH. Children/adolescents from 9 to 17 years of age received one dose.

In children from 6 months to 8 years of age, the safety profile 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.

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In children/adolescents from 9 to 17 years of age, the most frequently reported adverse reactions after vaccination were injection site pain (65.3%), myalgia (29.1%), headache (28.6%), malaise (20.3%), shivering (13.0%), injection site erythema (11.7%) and injection site swelling (11.4%).

In children from 3 to 8 years of age, the most frequently reported adverse reactions after any vaccination were injection site pain (59.1%), malaise (30.7%), injection site erythema (30.3%), myalgia (28.5%), headache (25.7%), injection site swelling (22.1%), injection site induration (17.6%), and shivering (11.2%).

In children from 6 to 35 months of age, the most frequently reported adverse reactions after any vaccination were injection site pain/tenderness (29.4%), fever (20.4%) and injection site erythema (17.2%).

- In subpopulation of children from 6 to 23 months of age, the most frequently reported adverse reactions after any vaccination were irritability (34.9%), crying abnormal (31.9%), appetite lost (28.9%), drowsiness (19.2%) and vomiting (17.0%).
- In subpopulation of children from 24 to 35 months of age, the most frequently reported adverse reactions after any vaccination was malaise (26.8%). myalgia (14.5%), headache (11.9%).

Table 2: Adverse reactions reported in children and adolescents from 6 months to 17 years of age

System Organ Class (SOC)/ Adverse Reactions	Frequency			
	Children 6-35 months of age		Children 3-8 years of age	Children and adolescents 9-17 years of age
	6-23 months of age	24-35 months of age		
Blood and Lymphatic System Disorders				
Lymphadenopathy	Not known*		Uncommon	Not known*
Thrombocytopenia	Not known*		Uncommon	Not known*
Immune System Disorders				
Allergic reactions such as:				
Oropharyngeal pain	-		Uncommon	-
Hypersensitivity	Uncommon		-	-
Rash	-		Uncommon	Uncommon
Urticaria	Not known*		Uncommon	Uncommon
Pruritus	Not known*		Uncommon	Not known*
Pruritus generalized, rash papular	Rare		-	-
Rash erythematous, dyspnoea, anaphylactic reaction, angioedema, shock	Not known*		Not known*	Not known*
Metabolism and Nutrition Disorders				
Decreased appetite	Very common	Rare	-	-
Psychiatric Disorders				
Crying abnormal	Very common	-	-	-
Irritability	Very common	Rare	-	-
Restlessness	-		Uncommon	-
Moaning	-		Uncommon	-
Nervous System Disorders				
Headache	-	Very common	Very common	Very common
Drowsiness	Very common	-	-	-
Dizziness	-		Uncommon	Uncommon

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System Organ Class (SOC)/ Adverse Reactions	Frequency			
	Children 6-35 months of age		Children 3-8 years of age	Children and adolescents 9-17 years of age
	6-23 months of age	24-35 months of age		
Neuralgia, neuritis and Guillain Barré Syndrome	-		Not known*	Not known*
Paraesthesia, convulsions, encephalomyelitis	Not known*		Not known*	Not known*
Vascular Disorders				
Vasculitis such as Henoch-Schonlein purpura, with transient renal involvement in certain cases	Not known*		Not known*	Not known*
Gastrointestinal Disorders				
Diarrhoea	Common		Uncommon	Uncommon
Abdominal pain	-		Uncommon	-
Vomiting	Very common	Uncommon	Uncommon	-
Musculoskeletal and Connective Tissue Disorders				
Myalgia	Rare	Very common	Very common	Very common
Arthralgia	-		Uncommon	-
General Disorders and Administration Site Conditions				
Injection site reactions				
Injection site pain/tenderness, injection site erythema	Very common		Very common	Very common
Injection site swelling	Common		Very common	Very common
Injection site induration	Common		Very common	Common
Injection site ecchymosis	Common		Common	Common
Injection site pruritus	Rare		Uncommon	Uncommon
Injection site warmth	-		Uncommon	Uncommon
Injection site discomfort	-		-	Uncommon
Injection site rash	Rare		-	-
Systemic reactions				
Malaise	Rare	Very common	Very common	Very common
Shivering	-	Common	Very common	Very common
Fever	Very common		Common	Common
Fatigue	-		Uncommon	Uncommon
Asthenia	-		-	Uncommon
Crying	-		Uncommon	-
Influenza-like illness	Rare			-

(*) Adverse reactions reported post-marketing after use of Vaxigrip TIV NH or Vaxigrip Tetra NH

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Other special populations

Although only a limited number of subjects with co-morbidities were enrolled, studies conducted in renal transplant patients or asthmatic patients, showed no major differences in terms of safety profile of Vaxigrip TIV NH in these populations. The safety profile of Vaxigrip Tetra NH 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.

Pregnant women

In clinical studies conducted in pregnant women in South Africa and Mali with Vaxigrip TIV NH (see Sections Fertility, pregnancy and lactation and Pharmacodynamic properties), frequencies of local and systemic solicited reactions reported within 7 days following administration of the vaccine, were consistent with those reported for the adult population during clinical studies. In the study conducted in South Africa, local reactions were more frequent in the Vaxigrip TIV NH 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 TIV NH and placebo groups in both cohorts.

In one clinical study conducted in pregnant women in Finland with Vaxigrip TIV NH and Vaxigrip Tetra NH (see Sections Fertility, pregnancy and lactation and Pharmacodynamic properties), frequencies of reported local and systemic solicited reactions were consistent with those reported for the non-pregnant adult population during clinical studies conducted with Vaxigrip TIV NH or Vaxigrip Tetra NH even though higher for some adverse reactions (injection site pain, injection site erythema, malaise, shivering, headache, myalgia).

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 reaction via farmakovigilans@kalventis.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/.

Overdose

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

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC code: J07BB02

Mechanism of action

Vaxigrip TIV NH provides active immunisation against three influenza virus strains (two A subtypes and one B type) contained in the vaccine.
Vaxigrip TIV NH induces humoral antibodies against the haemagglutinins within 2 to 3 weeks. These antibodies neutralise influenza viruses.
In infants less than 6 months of age born to women vaccinated with Vaxigrip TIV NH during pregnancy, protection is due to transplacental transfer of these neutralizing antibodies.
Specific levels of haemagglutination-inhibition (HAI) antibody titer post-vaccination with inactivated influenza virus vaccines have not been correlated with protection from influenza illness but the HAI antibody titers have been used as a measure of vaccine activity. In some human challenge studies, HAI

antibody titers 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.
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
Efficacy data of Vaxigrip TIV NH are available in pregnant women and in infants less than 6 months of age born to vaccinated pregnant women (passive protection).
No efficacy studies were performed with Vaxigrip TIV NH in children and adolescents from 9 to 17 years of age, in adults and in the elderly.
In children from 6 to 35 months of age and from 3 to 8 years of age (active immunisation), Vaxigrip TIV NH efficacy is based on extrapolation of Vaxigrip Tetra NH efficacy.

- *Infants less than 6 months of age born to vaccinated pregnant women (passive protection)*
Infants less than 6 months of age are at high risk of influenza, resulting in high rates of hospitalization; however influenza vaccines are not indicated for active immunisation in this age group.

Efficacy in infants of women who received a single 0.5 mL dose of Vaxigrip TIV NH during the second or third trimester of pregnancy has been demonstrated in clinical trials.
Efficacy of Vaxigrip TIV NH in infants following vaccination of pregnant women during the first trimester has not been studied in these trials. Necessary influenza vaccination during the first trimester should not be postponed (see Section Fertility, pregnancy and lactation).

In randomized, controlled phase IV clinical studies conducted in Mali, Nepal and South Africa, approximately 5,000 pregnant women received Vaxigrip TIV NH 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 TIV NH for the prevention of influenza in pregnant women following vaccination during these trimesters of pregnancy (see Table 3). In the study conducted in Nepal, the efficacy of Vaxigrip TIV NH for the prevention of influenza in pregnant women following vaccination during these trimesters of pregnancy was not demonstrated.

Table 3: Influenza Attack Rates and Vaxigrip TIV NH Efficacy against Laboratory-confirmed influenza in pregnant women

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

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

In the same randomized, controlled phase IV clinical studies conducted in Mali, Nepal and South Africa, 4530 of 4898 (92%) infants born to pregnant women who received Vaxigrip TIV NH and 4532 of 4868 (93%) infants born to pregnant women who received a placebo or control vaccine (quadrivalent

meningococcal conjugate vaccine) (see Table 2) during the second or third trimester of pregnancy, were followed up until approximately 6 months of age.

The studies confirmed the efficacy of Vaxigrip TIV NH for prevention of influenza in infants from birth until approximately 6 months of age following vaccination of women during these trimesters of pregnancy. Women in their first trimester of pregnancy were not included in these studies; Vaxigrip TIV NH efficacy in infants born to mothers vaccinated during the first trimester could therefore not be evaluated.

Table 4: Influenza Attack Rates and Vaxigrip TIV NH Efficacy against Laboratory-confirmed influenza in infants following vaccination in pregnant women

	Influenza Attack Rate (Any influenza A or B type) % (n/N)		**Vaxigrip TIV NH Efficacy % (95% CI)**
	TIV	**Control***	
Mali	2.4 (45/1,866)	3.8 (71/1,869)	37.3 (7.6 to 57.8)
	TIV	**Placebo**	
Nepal	4.1 (74/1,820)	5.8 (105/1,826)	30.0 (5 to 48)
South Africa	1.9 (19/1,026)	3.6 (37/1,023)	48.8 (11.6 to 70.4)

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

The efficacy data indicate a waning protection of the infants born to vaccinated mothers by 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 Vaxigrip TIV NH in infants during the first 4 months after birth, with lower efficacy within the 5th month of surveillance and a marked fall within the 6th month where protection is no longer evident.

The prevention of influenza disease can only be expected if the infant(s) are exposed to strains included in the vaccine administered to the mother.

- *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 Vaxigrip Tetra NH (N=2,722), or placebo (N=2,717) 28 days apart to assess Vaxigrip Tetra NH 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 5: Influenza Attack Rates and Vaxigrip Tetra NH Efficacy against laboratory-confirmed influenza illness in children from 6 to 35 months of age

	Vaxigrip Tetra NH (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 vaccin	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 Vaxigrip Tetra NH 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 Vaxigrip Tetra NH 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 of Vaxigrip Tetra NH observed in children 3 to 8 years of age, the efficacy of Vaxigrip Tetra NH 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 Vaxigrip Tetra NH" below).

Immunogenicity
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 of age described Vaxigrip TIV NH and Vaxigrip Tetra NH (QIV) 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 Vaxigrip Tetra NH and Vaxigrip TIV NH for HAI GMT at Day 21. Another clinical study performed in children from 9 to 17 years of age described the immune response of Vaxigrip Tetra NH.

One clinical study performed in pregnant women described the immune response of Vaxigrip Tetra NH and Vaxigrip TIV NH 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 the ratio of cord blood/maternal blood, at delivery.

Overall, Vaxigrip TIV NH induced a significant immune response to the 3 influenza strains contained in the vaccine.

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In children from 3 years of age, in adults including pregnant women and in the elderly, Vaxigrip TIV NH was as immunogenic as Vaxigrip Tetra NH for the strains in common.

- *Adults and elderly*

In one clinical study, the immune response was described in adults from 18 to 60 years of age and elderly over 60 years of age who received one 0.5-mL dose of Vaxigrip TIV NH or Vaxigrip Tetra NH. The immunogenicity results by HAI method in adults from 18 to 60 years of age and elderly over 60 years of age are presented in Table 6.

Table 6: Immunogenicity results in adults from 18 to 60 years of age and in elderly over 60 years of age, 21 days after vaccination with Vaxigrip or Vaxigrip Tetra

	Adults from 18 to 60 years of age			**Elderly over 60 years of age**		
Antigen Strain	**Alternative TIV [a] (B Victoria) N=140**	**Licensed TIV [b] (B Yamagata) N=138**	**QIV N=832**	**Alternative TIV [a] (B Victoria) N=138**	**Licensed TIV [b] (B Yamagata) N=137**	**QIV N=831**
GMT (95% CI)						
A (H1N1) [c][d]	685 (587; 800)		608 (563; 657)		268 (228; 314)	219 (199; 241)
A (H3N2) [c]	629 (543; 728)		498 (459; 541)		410 (352; 476)	359 (329; 391)
B (Victoria)	735 (615; 879)	-	708 (661; 760)	301 (244; 372)	-	287 (265; 311)
B (Yamagata)	-	1,735 (1,490; 2,019)	1,715 (1,607; 1,830)	-	697 (593; 820)	655 (611; 701)
SC % [e] (95% CI)						
A (H1N1) [c][d]	65.1 (59.2; 70.7)		64.1 (60.7; 67.4)		50.2 (44.1; 56.2)	45.6 (42.1; 49.0)
A (H3N2) [c]	73.4 (67.8; 78.5)		66.2 (62.9; 69.4)		48.5 (42.5; 54.6)	47.5 (44.1; 51.0)
B (Victoria)	70.0 (61.7; 77.4)	-	70.9 (67.7; 74.0)	43.5 (35.1; 52.2)	-	45.2 (41.8; 48.7)
B (Yamagata)	-	60.9 (52.2; 69.1)	63.7 (60.3; 67.0)	-	38.7 (30.5; 47.4)	42.7 (39.3; 46.2)
GMTR [f] (95% CI)						
A (H1N1) [c][d]	10.3 (8.35; 12.7)		9.77 (8.69; 11.0)		6.03 (4.93; 7.37)	4.94 (4.46; 5.47)
A (H3N2) [c]	14.9 (12.1; 18.4)		10.3 (9.15; 11.5)		5.79 (4.74; 7.06)	5.60 (5.02; 6.24)
B (Victoria)	11.4 (8.66; 15.0)	-	11.6 (10.4; 12.9)	4.60 (3.50; 6.05)	-	4.61 (4.18; 5.09)
B (Yamagata)	-	6.08 (4.79; 7.72)	7.35 (6.66; 8.12)	-	4.11 (3.19; 5.30)	4.11 (3.73; 4.52)

N = number of subjects with available data for the considered endpoint

GMT: Geometric mean titre; CI: Confidence interval;

(a) Alternative TIV containing A/California/7/2009 (H1N1), A/Texas/50/2012 (H3N2) and B/Brisbane/60/2008 (Victoria lineage)

(b) 2014-2015 licensed TIV containing A/California/7/2009 (H1N1), A/Texas/50/2012 (H3N2) and B/Massachusetts/2/2012 (Yamagata lineage)

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(c) The pooled TIV group includes participants vaccinated with either an alternative TIV or a licensed TIV, N = 278 for adults aged 18 to 60 years and N = 275 for the elderly aged over 60 years
(d) N = 833 for the QIV group in adults aged 18 to 60 years; N = 832 for the QIV group in the elderly aged over 60 years
(e) SC: seroconversion or significant increase: for subjects with a pre-vaccination titre

- *Pregnant women and transplacental transfer*

In one clinical study, a total of 116 pregnant women received Vaxigrip TIV NH and 230 pregnant women received Vaxigrip Tetra NH 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 Vaxigrip TIV NH or Vaxigrip Tetra NH are presented in Table 7.

Table 7: Immunogenicity results by HAI method in pregnant women, 21 days after vaccination with Vaxigrip TIV NH or Vaxigrip Tetra NH

Antigen Strain	TIV (B Victoria) N=109	QIV N=216
	GMT (95% CI	
A (H1N1)*	638 (529; 769)	525 (466; 592)
A (H3N2)*	369 (283; 483)	341 (286; 407)
B1 (Victoria)*	697 (569; 855)	568 (496; 651)
B2 (Yamagata)*	-	993 (870; 1134)
	≥4-fold-rise n (%) [(a)]	
A (H1N1)*	41.3 (31.9; 51.1)	38.0 (31.5; 44.8)
A (H3N2)*	62.4 (52.6; 71.5)	59.3 (52.4; 65.9)
B1 (Victoria)*	60.6 (50.7; 69.8)	61.1 (54.3; 67.7)
B2 (Yamagata)*	-	59.7 (52.9; 66.3)
	GMTR (95% CI) [(b)]	
A (H1N1)*	5.26 (3.66; 7.55)	3.81 (3.11; 4.66)
A (H3N2)*	9.23 (6.56; 13.0)	8.63 (6.85; 10.9)
B1 (Victoria)*	9.62 (6.89; 13.4)	8.48 (6.81; 10.6)
B2 (Yamagata)*	-	6.26 (5.12; 7.65)

N: number of subjects with available data for the considered endpoint
GMT: Geometric Mean Titer; CI: Confidence Interval
*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): this strain was included in the TIV composition;
B2: B/Phuket/3073/2013-like virus (B/Yamagata lineage): this strain was not included in the TIV composition.
(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)

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 8.

Table 8: Immunogenicity descriptive assessment by HAI method of Vaxigrip TIV NH or Vaxigrip Tetra NH, at delivery

Antigen Strain	TIV (B Victoria) N=89	QIV N=178
	BL03M (Maternal blood) GMT (95% CI)	
A (H1N1)*	411 (332; 507)	304 (265; 349)
A (H3N2)*	186 (137; 250)	178 (146; 218)

Antigen Strain	TIV (B Victoria) N=89	QIV N=178
B1 (Victoria)*	371 (299; 461)	290 (247; 341)
B2 (Yamagata)*	-	547 (463; 646)
	BL03B (Cord blood) GMT (95% CI)	
A (H1N1)*	751 (605; 932)	576 (492; 675)
A (H3N2)*	324 (232; 452)	305 (246; 379)
B1 (Victoria)*	608 (479; 772)	444 (372; 530)
B2 (Yamagata)*		921 (772; 1099)
	Transplacental transfer: BL03B/BL03M GMT (95% CI)**	
A (H1N1)*	1.83 (1.64; 2.04)	1.89 (1.72; 2.08)
A (H3N2)*	1.75 (1.55; 1.97)	1.71 (1.56; 1.87)
B1 (Victoria)*	1.64 (1.46; 1.85)	1.53 (1.37; 1.71)
B2 (Yamagata)*	-	1.69 (1.54; 1.85)

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.
GMT: Geometric Mean Titer; CI: Confidence Interval
*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): this strain was included in the TIV composition;
B2: B/Phuket/3073/2013-like virus (B/Yamagata lineage): this strain was not included in the TIV composition.
** If a mother have X babies, her titers values is counted X times

At delivery, the higher level of antibodies in the cord sample compared to the maternal sample is consistent with transplacental antibody transfer from mother to the newborn following vaccination of women with Vaxigrip TIV NH or Vaxigrip Tetra NH 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 NH in studies conducted in Mali, Nepal, and South Africa (see subsection Efficacy).

- *Pediatric population*

- Children from 9 to 17 years of age

In a total of 55 children from 9 to 17 years of age who received one dose of Vaxigrip TIV NH and 429 who received one dose of Vaxigrip Tetra NH, the immune response against the strains contained in the vaccine was similar to the immune response induced in adults 18 to 60 years of age.

- Children from 3 years to 8 years of age

In one clinical study, the immune response was described in children from 3 to 8 years of age who received either one or two 0.5-ml doses of Vaxigrip TIV NH or Vaxigrip Tetra NH, depending on their previous influenza vaccination history.
Children who received a one- or two-dose schedule of Vaxigrip TIV NH or Vaxigrip Tetra NH presented a similar immune response following the last dose of the respective schedule.
The immunogenicity results by HAI method 28 days after receipt of the last injection are presented in Table 9.

- Children from 6 months to 35 months of age

In one clinical trial, the immune response was described in children from 6 to 35 months of age who received two 0.5-mL doses of Vaxigrip TIV NH or Vaxigrip Tetra NH.

Immunogenicity results by HAI method, 28 days after receipt of the last injection are presented in Table 9.

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Table 9: immunogenicity results in children from 6 months to 35 months of age and from 3 to 8 years of age, 28 days after the last injection of Vaxigrip TIV NH or Vaxigrip Tetra NH

	Children from 6 to 35 months of age			Children from 3 to 8 years of age		
Antigen Strain	**Alternative TIV [a] (B Victoria) N=172**	**Licensed TIV [b][c] (B Yamagata) N=178**	**QIV N=341**	**Alternative TIV [a] (B Victoria) N=176**	**Licensed TIV [b] (B Yamagata) N=168**	**QIV N=863**
GMT (95% CI)						
A (H1N1) [d]	685 (587; 800)		608 (563; 657)		268 (228; 314)	219 (199; 241)
A (H3N2) [d]	629 (543; 728)		498 (459; 541)		410 (352; 476)	359 (329; 391)
B (Victoria) [e]	735 (615; 879)	-	708 (661; 760)	301 (244; 372)	-	287 (265; 311)
B (Yamagata) [f][g]	-	1,735 (1,490; 2,019)	1,715 (1,607; 1,830)	-	697 (593; 820)	655 (611; 701)
SC % [e] (95% CI)						
A (H1N1) [d]	65.1 (59.2; 70.7)		64.1 (60.7; 67.4)		50.2 (44.1; 56.2)	45.6 (42.1; 49.0)
A (H3N2) [d]	73.4 (67.8; 78.5)		66.2 (62.9; 69.4)		48.5 (42.5; 54.6)	47.5 (44.1; 51.0)
B (Victoria) [e]	70.0 (61.7; 77.4)	-	70.9 (67.7; 74.0)	43.5 (35.1; 52.2)	-	45.2 (41.8; 48.7)
B (Yamagata) [f][g]	-	60.9 (52.2; 69.1)	63.7 (60.3; 67.0)	-	38.7 (30.5; 47.4)	42.7 (39.3; 46.2)
GMTR [f] (95% CI)						
A (H1N1) [d]	10.3 (8.35; 12.7)		9.77 (8.69; 11.0)		6.03 (4.93; 7.37)	4.94 (4.46; 5.47)
A (H3N2) [d]	14.9 (12.1; 18.4)		10.3 (9.15; 11.5)		5.79 (4.74; 7.06)	5.60 (5.02; 6.24)
B (Victoria) [e]	11.4 (8.66; 15.0)	-	11.6 (10.4; 12.9)	4.60 (3.50; 6.05)	-	4.61 (4.18; 5.09)
B (Yamagata) [f][g]	-	6.08 (4.79; 7.72)	7.35 (6.66; 8.12)	-	4.11 (3.19; 5.30)	4.11 (3.73; 4.52)

N = number of subjects with available data for the considered endpoint
GMT: Geometric mean titre; CI: Confidence interval;
(a) Alternative TIV containing A/California/7/2009 (H1N1), A/Texas/50/2012 (H3N2) and B/Brisbane/60/2008 (Victoria lineage)
(b) 2014-2015 licensed TIV containing A/California/7/2009 (H1N1), A/Texas/50/2012 (H3N2) and B/Massachusetts/2/2012 (Yamagata lineage)
(c) Dose of 0.5 mL in children 6 to 35 months of age
(d) For children 3 to 8 years of age: The TIV group includes participants vaccinated with either alternative TIV or licensed TIV, N = 344
(e) N = 169 for Vaxigrip (B Victoria) group in children 3 to 8 years of age
(f) N = 862 for QIV group in children 3 to 8 years of age
(g) For alternative TIV (B Victoria) group: N = 171 for children 6 to 35 months of age; N = 175 for children 3 to 8 years of age
(h) SC: seroconversion or significant increase: for subjects with a pre-vaccination titre

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These immunogenicity data provide supportive information in addition to efficacy data available in ~~this population~~ children from 6 to 35 months of age (see Section Efficacy).

Pharmacokinetic properties
Not applicable.

Preclinical safety data
Data in animals generated with Vaxigrip Tetra NH (60 µg of total amount HA/dose) can be extrapolated to Vaxigrip TIV NH (45 µg of total amount HA/dose): these data revealed no unexpected findings and no target organ toxicity.

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.

Shelf life
1 year.

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.

Vaxigrip TIV NH remains stable for 72 hours at temperatures up to 25°C ± 2°C. This is not a recommended storage condition; it is only intended to guide healthcare professionals in case of temporary temperature excursion

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.

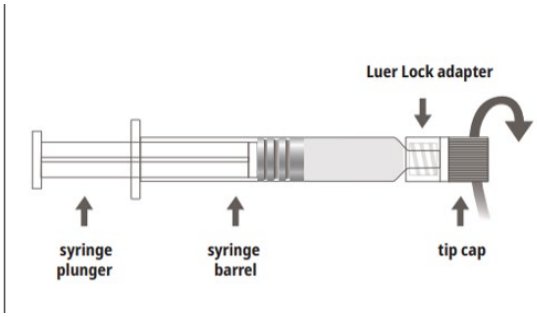
Preparation for administration:
The syringe containing the suspension for injection must be visually inspected before administration. In the event of foreign particles, leakage, premature activation of the plunger or a faulty tip, discard the pre-filled syringe.

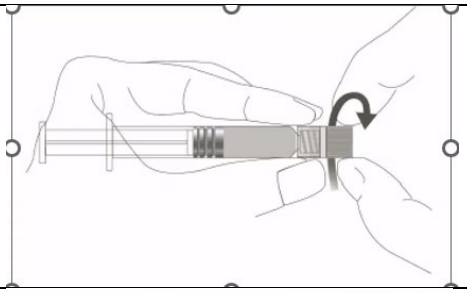
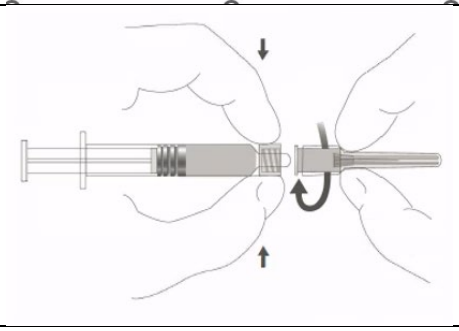
The syringe is intended for single use only and must not be reused.

Instructions for use for the luer lock pre-filled syringe.

Picture A: Luer Lock syringe with Rigid Tip Cap

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Step 1: Holding the Luer Lock adapter in one hand (avoid holding the syringe plunger or barrel), unscrew the tip cap by twisting it.	
Step 2: To attach the needle to the syringe, gently twist the needle into the Luer Lock adapter of the syringe until slight resistance is felt.	

Packaging Presentation
Box, 1 pre-filled syringe @ 0.5 mL
Reg No. DKI2559704043A1

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

Registered by:
PT Kalventis Sinergi Farma, Jakarta - Indonesia

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VAXIGRIP TIV NH

TRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)

Suspensi untuk injeksi dalam *pre-filled syringe*

Bacalah seluruh leaflet ini dengan seksama sebelum Anda divaksinasi karena isi dalam selebaran ini mengandung informasi yang penting bagi Anda.

- Simpan leaflet ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter atau apoteker Anda.
- Vaksin ini telah diresepkan secara khusus 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.

Apa saja informasi dalam leaflet ini:

1. Apa itu VAXIGRIP TIV NH dan digunakan untuk apa
2. Informasi yang perlu Anda ketahui sebelum Anda atau anak Anda menggunakan VAXIGRIP TIV NH
3. Aturan pakai VAXIGRIP TIV NH
4. Efek samping yang mungkin dapat terjadi
5. Cara menyimpan VAXIGRIP TIV NH
6. Informasi lebih lanjut

1. APA ITU VAXIGRIP TIV NH DAN APA KEGUNAANNYA

VAXIGRIP TIV NH merupakan suspensi untuk injeksi dalam *prefilled syringe* 0.5 mL dalam 1 dus. Vaksin ini digunakan untuk pencegahan influenza (flu) pada orang dewasa dan anak mulai dari usia 6 bulan. Penggunaan vaksin ini harus sesuai dengan rekomendasi dari dokter atau apoteker Anda atau anak Anda.

Ketika Anda atau anak Anda mendapat vaksin VAXIGRIP TIV NH sistem imun tubuh akan secara alami memproduksi antibodi untuk melawan virus influenza. Ketika diberikan selama kehamilan, vaksin ini membantu melindungi wanita hamil dan juga membantu melindungi bayinya dari lahir hingga kurang dari 6 bulan melalui transmisi perlindungan dari ibu ke bayi selama kehamilan (lihat juga Bagian 2 dan 3).

Tidak ada satupun bahan dari vaksin ini yang dapat menyebabkan flu.

Penggunaan Vaxigrip TIV NH harus berdasarkan rekomendasi resmi dari dokter.

Flu merupakan sebuah penyakit yang penyebarannya cepat dan disebabkan oleh berbagai tipe virus yang dapat berubah setiap tahunnya. Karena potensi perubahan strain yang beredar setiap tahun, serta durasi perlindungan yang dimaksudkan oleh vaksin, vaksinasi direkomendasikan setiap tahun. Dokter Anda akan menentukan waktu terbaik untuk Anda atau anak Anda menjalankan vaksinasi. VAXIGRIP TIV NH dimaksudkan untuk melindungi Anda atau anak Anda melawan tiga jenis virus yang terdapat di dalam vaksin ini sekitar 2 sampai 3 minggu setelah penyuntikan.

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Selain itu, jika Anda atau anak Anda terpapar flu segera sebelum atau setelah vaksinasi Anda, Anda atau anak Anda masih dapat terinfeksi penyakit ini karena masa inkubasi flu dapat berlangsung hingga beberapa hari. Vaksin ini tidak akan melindungi Anda atau anak Anda dari flu biasa, meskipun beberapa gejalanya mirip dengan flu.

2. INFORMASI YANG PERLU ANDA KETAHUI SEBELUM MENGGUNAKAN VAXIGRIP TIV NH

Jangan gunakan VAXIGRIP TIV NH jika Anda atau anak Anda:

- Alergi dengan bahan aktif, atau dengan salah satu bahan tambahan, atau dengan komponen lainnya yang terkandung dengan jumlah yang sangat kecil seperti telur (ovalbumin atau protein ayam), atau dengan neomycin, formaldehyde dan octoxinol-9.
- Mengalami demam derajat sedang atau berat atau penyakit akut.

Perhatian khusus menggunakan VAXIGRIP TIV NH

Informasikan kepada dokter atau apoteker Anda sebelum menggunakan VAXIGRIP TIV NH.
Informasikan kepada dokter anda jika Anda atau anak Anda:

- Memiliki respon imun yang lemah (gangguan sistem imun atau mengkonsumsi obat-obatan yang berdampak pada sistem imun)
- Mengalami masalah perdarahan atau mudah memar

Dokter Anda akan memutuskan apakah Anda atau anak Anda dapat melakukan vaksinasi.
Pingsan dapat terjadi setelah atau sebelum vaksinasi apa pun sebagai respon psikogenik terhadap suntikan jarum. Oleh karena itu, beri tahu dokter atau perawat jika Anda atau anak Anda pernah pingsan setelah penyuntikan sebelumnya.
Seperti semua vaksin, Vaxigrip TIV NH mungkin tidak sepenuhnya melindungi semua orang yang divaksinasi.
Tidak semua bayi yang berusia kurang dari 6 bulan yang lahir dari wanita hamil yang divaksinasi selama kehamilan akan terlindungi.

Anak-anak:

VAXIGRIP TIV NH tidak diindikasikan pada anak berusia di bawah 6 bulan.

Penggunaan VAXIGRIP TIV NH bersama dengan obat lain:

Informasikan kepada dokter atau apoteker Anda jika Anda atau anak Anda baru saja mengkonsumsi obat atau vaksin lain.

- VAXIGRIP TIV NH dapat diberikan pada waktu yang sama dengan vaksin lain dengan menggunakan lokasi penyuntikan yang terpisah.
- Respon imunologi mungkin menurun pada pasien yang menerima obat imunosupresif seperti kortikosteroid, obat sitotoksik atau radioterapi.

Selama Kehamilan dan Menyusui:

Jika Anda sedang hamil atau menyusui, atau berpikir bahwa Anda mungkin hamil, tanyakan kepada dokter atau apoteker untuk saran sebelum menggunakan vaksin ini.

- VAXIGRIP TIV NH dapat digunakan pada semua tahap kehamilan.
- VAXIGRIP TIV NH dapat digunakan selama menyusui.

Dokter atau apoteker Anda akan dapat memutuskan apakah Anda harus menerima Vaxigrip TIV NH.

Mengemudi dan Mengoperasikan Mesin:
VAXIGRIP TIV NH tidak berpengaruh terhadap kemampuan dalam mengemudi dan mengoperasikan mesin.

VAXIGRIP TIV NH mengandung kalium dan natrium:
Vaksin ini mengandung kurang dari 1 mmol kalium (39 mg) dan natrium (23 mg) per dosis, yaitu pada dasarnya 'bebas kalium' dan 'bebas natrium'.

3. ATURAN PAKAI VAXIGRIP TIV NH

Dosis:
Dosis dewasa yang direkomendasikan adalah 0.5 mL tiap injeksi.

Penggunaan pada anak-anak dan remaja:
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 sebelumnya terhadap flu, dosis kedua sebesar 0,5 mL harus diberikan setelah minimal 4 minggu.
Jika Anda sedang hamil, satu dosis 0,5 mL yang diberikan kepada Anda selama kehamilan dapat melindungi bayi Anda dari lahir hingga usia kurang dari 6 bulan. Tanyakan kepada dokter atau apoteker Anda untuk informasi lebih lanjut.

Cara pemberian VAXIGRIP TIV NH:
Dokter atau perawat Anda akan memberikan dosis yang dianjurkan dari vaksin ini sebagai penyuntikan ke dalam otot atau di bawah kulit.

Jika Anda atau anak Anda menerima lebih banyak Vaxigrip TIV NH daripada yang seharusnya:
Dalam beberapa kasus, lebih dari dosis yang dianjurkan telah diberikan secara tidak sengaja.
Dalam kasus ini, ketika efek samping dilaporkan, efek samping tersebut sejalan dengan apa yang dijelaskan setelah pemberian dosis yang dianjurkan (lihat Bagian 4).
Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan produk ini, tanyakan kepada dokter atau apoteker Anda.

4. EFEK SAMPING YANG MUNGKIN DAPAT TERJADI

Seperti semua produk obat, VAXIGRIP TIV NH dapat menyebabkan efek samping yang tidak diinginkan, meskipun tidak semua orang mengalaminya.
Jika Anda mengalami reaksi alergi, segera hubungi dokter atau tenaga medis Anda atau pergi ke ruang gawat darurat rumah sakit terdekat.

Reaksi Alergi
Reaksi alergi dapat terjadi segera setelah pemberian vaksin dan mungkin mengancam nyawa.

Gejala mungkin termasuk:
- Ruam, gatal, kesulitan bernapas, sesak napas, pembengkakan pada wajah, bibir, tenggorokan, atau lidah, tekanan darah rendah, denyut jantung cepat dan nadi lemah, kulit dingin dan lembap, pusing, kelemahan atau pingsan (reaksi anafilaksis, angioedema, syok).

Gejala lain mungkin termasuk:
- Area kulit yang gatal, merah, bengkak, dan pecah-pecah (dermatitis atopi), kemerahan, perasaan panas, darah di putih mata (hiperemia okular), kemerahan dan iritasi mata (konjungtivitis), iritasi tenggorokan, sakit tenggorokan, iritasi di dalam hidung, pilek, bersin, hidung tersumbat, sinus atau tenggorokan, kebas atau sensasi kesemutan di mulut (parestesia oral), ruam di mulut (erupsi mukosa oral), asma.

Reaksi alergi ini dilaporkan sebagai tidak umum (dapat mempengaruhi hingga 1 dari 100 orang) hingga jarang (dapat mempengaruhi hingga 1 dari 1.000 orang).

Efek samping tambahan pada dewasa dan lansia
Sangat umum (dapat mempengaruhi lebih dari 1 dari 10 orang):
- Sakit kepala, nyeri otot, merasa tidak enak badan secara umum (malaise) [(1)], nyeri di lokasi penyuntikan

(1) Umum pada lansia

Umum (dapat mempengaruhi hingga 1 dari 10 orang):
- Demam [(2)], menggigil, reaksi di lokasi penyuntikan: kemerahan (eritema), kekerasan (indurasi), pembengkakan

(2) Tidak umum pada lansia

Tidak umum (dapat mempengaruhi hingga 1 dari 100 orang):
- Pembengkakan kelenjar di leher, ketiak, atau selangkangan (limfadenopati) [(3)], kelemahan yang tidak biasa [(3)], kelelahan, rasa mengantuk [(4)], pusing [(4)], peningkatan berkeringat (hiperhidrosis) [(3)], nyeri sendi [(3)], diare, merasa mual (nausea), reaksi di lokasi penyuntikan: memar, gatal, rasa hangat, ketidaknyamanan

(3) Jarang pada lansia (4) Jarang pada dewasa

Jarang (dapat mempengaruhi hingga 1 dari 1.000 orang):
- Kebas atau sensasi kesemutan (parestesia), muntah, nafsu makan menurun, penyakit seperti flu
- Penurunan sensitivitas (hipoestesia), nyeri perut, alergi di lokasi penyuntikan: hanya terlihat pada dewasa
- Kulit terkelupas (eksfoliasi) di lokasi penyuntikan: hanya terlihat pada lansia.

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Efek samping tambahan pada anak-anak usia 3 hingga 17 tahun

Sangat umum (dapat mempengaruhi lebih dari 1 dari 10 orang):

- Sakit kepala, nyeri otot, merasa tidak enak badan secara umum, menggigil, reaksi di lokasi penyuntikan: nyeri, kemerahan, pembengkakan, kekerasan [5]

(5) Umum pada anak-anak usia 9 hingga 17 tahun

Umum (dapat mempengaruhi hingga 1 dari 10 orang):

- Demam, memar di lokasi penyuntikan

Tidak umum (dapat mempengaruhi hingga 1 dari 100 orang):

- Kelelahan, pusing, diare, reaksi di lokasi penyuntikan: gatal, rasa hangat
- Pembengkakan kelenjar di leher, ketiak, atau selangkangan, nyeri perut, muntah, kegelisahan, rintihan, nyeri sendi, menangis: hanya terlihat pada anak-anak usia 3 hingga 8 tahun.
- Penurunan jumlah jenis partikel tertentu dalam darah yang disebut trombosit; jumlah yang rendah dapat mengakibatkan memar atau perdarahan berlebihan (trombositopenia): hanya terlihat pada satu anak usia 3 tahun.
- Kelemahan yang tidak biasa, ketidaknyamanan di lokasi penyuntikan: hanya terlihat pada anak-anak usia 9 hingga 17 tahun.

Efek samping tambahan pada anak-anak usia 6 hingga 35 bulan

Sangat umum (dapat mempengaruhi lebih dari 1 dari 10 orang):

- Irritability [6], muntah [7], nyeri otot [8], merasa tidak enak badan secara umum [8], demam, penurunan nafsu makan [6], reaksi di lokasi penyuntikan: nyeri, kemerahan
- Menangis tidak biasa, mengantuk: hanya terlihat pada anak-anak kurang dari 24 bulan.
- Sakit kepala: hanya terlihat pada anak-anak usia 24 bulan ke atas

(6) Jarang pada anak-anak usia 24 hingga 35 bulan (7) Tidak umum pada anak-anak usia 24 hingga 35 bulan (8) Jarang pada anak-anak usia 6 hingga 23 bulan

Umum (dapat mempengaruhi hingga 1 dari 10 orang):

- Diare, reaksi di lokasi penyuntikan: kekerasan, memar, pembengkakan
- Menggigil: hanya terlihat pada anak-anak usia 24 bulan ke atas.

Jarang (dapat mempengaruhi hingga 1 dari 1.000 orang):

- Penyakit seperti flu, reaksi di lokasi penyuntikan: gatal, ruam

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

Kebanyakan efek samping biasanya terjadi dalam 3 hari setelah vaksinasi dan hilang dalam 1 hingga 3 hari tanpa perawatan. Intensitas sebagian besar efek samping ini ringan hingga sedang.

Secara keseluruhan, efek samping umumnya kurang sering terjadi pada lansia dibandingkan pada dewasa dan anak-anak.

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Frekuensi efek samping berikut tidak diketahui (tidak dapat diperkirakan dari data yang tersedia) di seluruh populasi kecuali pada populasi di mana efek samping tersebut disebutkan di atas:

- Pembengkakan kelenjar di leher, ketiak, atau selangkangan
- Kebas atau sensasi kesemutan (parestesia), nyeri yang terletak pada jalur saraf (neuralgia) (9), kejang (konvulsi), gangguan neurologis yang dapat mengakibatkan kekakuan tenggorokan, kebingungan, kebas, nyeri dan kelemahan anggota badan, kehilangan keseimbangan, kehilangan refleks, kelumpuhan sebagian atau seluruh tubuh, ensefalomielitis, neuritis (9), Sindrom Guillain-Barré (9)
- Peradangan pembuluh darah (vasculitis) yang dapat mengakibatkan ruam kulit dan dalam kasus yang sangat jarang menyebabkan masalah ginjal sementara
- Penurunan sementara jumlah jenis partikel tertentu dalam darah yang disebut trombosit; jumlah yang rendah dapat mengakibatkan memar atau perdarahan berlebihan (trombositopenia sementara).

(9) Tidak dilaporkan pada anak-anak usia 6 hingga 35 bulan

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.
Anda juga dapat melaporkan efek samping secara langsung ke Industri Farmasi dengan kontak berikut farmakovigilans@kalventis.com.
Dengan melaporkan efek samping Anda dapat membantu memberikan informasi tentang keamanan obat ini.

5. CARA MENYIMPAN VAXIGRIP TIV NH

Simpan vaksin ini di luar jangkauan dan penglihatan anak-anak.
Produk harus disimpan terlindung dari cahaya pada suhu antara 2°C dan 8°C di kulkas).
Vaksin ini tidak boleh dibekukan.
Letakkan syringe di dalam dus agar tetap terlindung dari cahaya.
Jangan gunakan produk ini setelah tanggal kedaluwarsa yang tercantum pada dus.
Tanyakan pada apoteker Anda cara pengolahan produk yang sudah tidak digunakan.

6. INFORMASI LEBIH LANJUT

Apa yang terkandung dalam VAXIGRIP TIV NH

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/Darwin/9/2021 (H3N2)-like virus (A/Darwin/9/2021, IVR-228)
……..……..……..... 15 mikrogram HA**
B/Austria/1359417/2021-like virus (B/Michigan/01/2021, 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 Utara) dan keputusan EU untuk musim 202X/202X.
- Bahan lain adalah: larutan penyangga yang mengandung natrium klorida, disodium fosfat dihidrat, kalium dihidrogen fosfat, kalium klorida , 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 bentuk VAXIGRIP TIV NH dan isi kemasannya
Vaksin, setelah dikocok dengan perlahan, adalah cairan opalescent tak berwarna. Bentuk sediaan adalah suspensi untuk injeksi dengan kemasan sebagai berikut:

Kemasan:
Dus, 1 *pre-filled syringe* @ 0.5 mL
No. Registrasi: DKI2559704043A1

HARUS DENGAN RESEP DOKTER

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

Didaftarkan oleh: PT Kalventis Sinergi Farma, Jakarta - Indonesia

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