PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

VAXIGRIP TETRA 2025 strains, suspension for injection

Quadrivalent influenza vaccine (split virion, inactivated).

Sugar free.

Read all of this leaflet carefully before you or your child is vaccinated, because it contains important information for you.

VAXIGRIP TETRA is available without a doctor's prescription, for you or your child to protect you against influenza (flu).

Nevertheless, you still need to use VAXIGRIP TETRA carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share VAXIGRIP TETRA with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- If you or your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet

1. What VAXIGRIP TETRA is and what it is used for

This vaccine complies with the WHO recommendations (Southern Hemisphere) for the 2025 season.

VAXIGRIP TETRA may contain traces of eggs, such as ovalbumin and of neomycin, formaldehyde and octoxinol-9, which are used during the manufacturing process.

VAXIGRIP TETRA is intended to protect you or your child from 6 months of age against influenza (flu).

When you or your child is given VAXIGRIP TETRA, the immune system (the body's natural defence system) will produce its own protection (antibodies) against the disease.

When given during pregnancy, VAXIGRIP TETRA helps to protect you, but also helps to protect your baby from birth up to 6 months of age through the transmission of protection from mother to baby during pregnancy (see also sections 2 and 3).

None of the ingredients in the vaccine can cause flu.

VAXIGRIP TETRA is intended to protect you or your child against the four strains of virus contained in the vaccine about 2 to 3 weeks following the injection. The four strains of virus are made up of 2 influenza A subtypes and two influenza B types. However, if you or your child is exposed to flu immediately before or after your vaccination, you or your child could still develop the illness as the incubation period for flu is a few days.

2. What you need to know before you or your child is given VAXIGRIP TETRA

VAXIGRIP TETRA should not be administered:

- If you or your child has a history of severe allergic reaction (which may have required medical attention) to:
  - the active substances, or
  - any of the other ingredients of this vaccine (listed in **What VAXIGRIP TETRA contains**), or
  - any component that may be present in very small amounts such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde or octoxinol-9.

- If you or your child has a history of severe allergic reaction after a previous administration of VAXIGRIP TETRA or a vaccine containing the same ingredients (listed in **What VAXIGRIP TETRA contains**).
- If you or your child has an illness with a high or moderate temperature or an acute illness, the vaccination should be postponed until after you or your child has recovered.

Warnings and precautions

Tell your doctor or health care provider before being vaccinated with VAXIGRIP TETRA:

- Vaccination with VAXIGRIP TETRA may not protect 100 % of susceptible individuals.
- VAXIGRIP TETRA should not be given by intravenous route.
- Influenza virus is remarkably unpredictable in that significant antigenic changes may occur from time to time. It is known that VAXIGRIP TETRA, as constituted per annual seasonal composition, is not effective against all possible strains of influenza virus.
- VAXIGRIP TETRA is intended to provide protection against those strains of virus from which the vaccine is prepared.
- If the vaccine is used in persons deficient in producing antibodies, whether due to genetic defect, immunodeficiency disease, or immunosuppressive therapy, the expected immune response may not be obtained.
- Bleeding might occur following intramuscular injection; inform your health care provider if you have a bleeding disorder.
- Fainting can occur following, or even before any needle injection. Therefore, tell your health care provider if you or your child fainted with a previous injection.
- Not all babies less than 6 months of age, born to pregnant women who were vaccinated during pregnancy, will be protected.
- If, for any reason, you or your child has a blood test within a few days following a flu vaccination, please tell your doctor or health care provider. This is because false positive blood test results have been observed in a few patients who had recently been vaccinated.

Children

VAXIGRIP TETRA is not recommended for use in children below 6 months of age.

Other medicines and VAXIGRIP TETRA:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

No studies regarding the simultaneous administration of VAXIGRIP TETRA and other vaccines have been conducted.

Nevertheless, clinical data showing that VAXIGRIP TETRA or VAXIGRIP can be administered concomitantly with other vaccines are available for the following vaccines: Pneumococcal polysaccharide vaccine in elderly patients, Tdap-IPV (Adacel QUADRA®) in adults aged ≥ 60 years and zoster vaccine (Zostavax®) in adults aged 50 years and older.

In addition, according to Advisory Committee on Immunisation Practices (ACIP), there is no evidence that inactivated vaccines interfere with the immune response to other inactivated vaccines or to live vaccines. Any inactivated vaccine can be administered either simultaneously or at any time before or after a different inactivated vaccine or live vaccine.

Separate injection sites and separate syringes should be used. The immune response to VAXIGRIP TETRA may be reduced by immunosuppressant treatment due to a deficit in producing antibodies.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving VAXIGRIP TETRA.

Pregnancy:

One developmental and reproductive toxicity study conducted in rabbits with VAXIGRIP TETRA did not show any effects on mating performance, embryo-fetal development and early postnatal development. For VAXIGRIP TETRA, no clinical trial data on exposed pregnancies are available. Pregnant women are at high risk of influenza complications, including premature labour and delivery, hospitalisation, and death.

Based on safety and efficacy data from clinical trials conducted with the Sanofi Pasteur trivalent influenza vaccine, VAXIGRIP, and from post-marketing experience with VAXIGRIP, VAXIGRIP TETRA can be administered in all stages of pregnancy.

Data from four clinical studies conducted with VAXIGRIP 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 post-partum), did not indicate any adverse fetal, newborn, infant or maternal outcomes attributable to the vaccine.

Breastfeeding:

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

Driving and using machines:

VAXIGRIP TETRA has no or negligible influence on the ability to drive a vehicle and use machines.

3. How to receive VAXIGRIP TETRA

You will not be expected to give yourself VAXIGRIP TETRA, it will be given to you by a person who is qualified to do so. Given the antigenic variation in circulating influenza viruses and the duration of immunity provided by the vaccine, it is recommended to perform vaccination against influenza every year at the beginning of the risk period.

Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of VAXIGRIP TETRA.

The vaccine should be allowed to reach room temperature before use. Parenteral medicines should be inspected visually for particulate matter and/or discolouration prior to administration whenever solution and container permit. **If either of these conditions exists, the vaccine should not be administered. Shake before use.**

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 TETRA administration (active immunisation) have not been established. No data are available.

  If you are pregnant: one 0,5 mL dose given to you during pregnancy may protect your baby from birth up to 6 months of age. Ask your doctor or pharmacist for more information.

The vaccine should be given by intramuscular or deep subcutaneous injection.

If you take more VAXIGRIP TETRA than you should:

Not documented.

Since a health care provider will administer VAXIGRIP TETRA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

VAXIGRIP TETRA can cause side effects, although not everybody gets them.

Not all side effects reported for VAXIGRIP TETRA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving VAXIGRIP TETRA, please consult your doctor, pharmacist or other health care provider for advice.

See a doctor immediately or go to the casualty department at your nearest hospital if you or your child experiences:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you or your child has them, you or your child may have had a serious reaction to VAXIGRIP TETRA. You may need urgent medical attention or hospitalisation.

Data from clinical studies

Side effects reported within 7 days after vaccination during clinical trials with VAXIGRIP TETRA:

Adults (18 to 60 years)

Frequently occurring:

- headache, muscle pain (myalgia), discomfort or uneasiness (malaise), injection site pain, fever, shivering, injection site reactions: redness (erythema), swelling, hardening (induration).

Less frequently occurring:

- injection site bruising (ecchymosis).

Elderly patients (over 60 years)

Frequently occurring:

- headache, muscle pain, injection site pain
- shivering, discomfort or uneasiness, injection site reactions: redness, swelling, hardening.

Less frequently occurring:

- fever, injection site bruising.

Children and adolescents 9 to 17 years

Frequently occurring:

- headache, muscle pain, discomfort or uneasiness, injection site reactions: pain and swelling
- shivering, fever, injection site reactions: redness, hardening, bruising.

Children 3 to 8 years:

Frequently occurring:

- headache, muscle pain, discomfort or uneasiness, shivering, injection site reactions: pain, swelling, redness, hardening
- fever, injection site bruising.

Most of the side effects usually occurred within the 3 days following vaccination and disappeared within 1 to 3 days after onset without treatment. The intensity of these reactions was mild. Overall, side effects were generally less frequent in elderly patients than in adults and in children from 3 to 17 years.

Safety evaluations were performed during the first 21 days after vaccination in adolescents from 9 to 17 years old, adults and elderly patients over 60 years old; and 28 days after vaccination in children from 3 to 8 years old during clinical trials with VAXIGRIP TETRA. The side effects reported occurred less frequently.

Adults (18 to 60 years)

Less frequently occurring:

- injection site itching and warmth, fatigue, diarrhoea, nausea, swelling of the glands in the neck, armpit or groin (lymphadenopathy)

- injection site discomfort, influenza-like illness, unusual tiredness and weakness (asthenia), breathing difficulty (dyspnoea), dizziness, abnormal sensation of touch, pain, heat and cold (paraesthesia), drowsiness (somnolence), excessive sweating (hyperhidrosis), hives (urticaria), severe allergic reaction which causes swelling of the face or throat (angioedema), itching, generalised itching, red itchy rash (allergic dermatitis), redness, joint pain (arthralgia), allergy (hypersensitivity).

Elderly patients (over 60 years)

Less frequently occurring:

- injection site itching and warmth, fatigue, diarrhoea, dizziness, hot flushes, itching, unusual tiredness and weakness, influenza-like illness, nausea, abnormal sensation of touch, pain, heat and cold, drowsiness, redness, excessive sweating (hyperhidrosis).

Children and adolescents (9 to 17 years)

Less frequently occurring:

- injection site itching, diarrhoea.

Children (6 to 35 months) – side effects reported within 28 days after vaccination with VAXIGRIP TETRA:

Frequently occurring:

- vomiting[(1)], muscular pain (myalgia)[(2)], irritability[(1)], appetite loss[(1)], generally feeling unwell (malaise)[(2)], fever

  [(1)] Less frequently occurring in children from 24 to 35 months of age

  [(2)] Less frequently occurring in children less than 24 months of age
- reactions at the injection site: pain/tenderness, redness (erythema)
- headache (only seen in children from 24 months of age)
- drowsiness, unusual crying (only seen in children less than 24 months of age)

- shivering (only seen in children 24 months and older)
- reactions at the injection site: hardness (induration), swelling, bruising (ecchymosis).

Less frequently occurring:

- Fatigue, injection site warmth, diarrhoea, vomiting, upper abdominal pain, restlessness, moaning, dizziness, joint pain, temporary reduction in the number of certain types of particles called platelets; a low number of these can result in excessive bruising or bleeding (thrombocytopenia).

Data from post-marketing experience

No safety data have been collected from post-marketing experience with VAXIGRIP TETRA.

The following side effects have been reported with VAXIGRIP (trivalent) and may occur in people receiving VAXIGRIP TETRA:

- Severe allergic reactions that may lead to medical emergency with low blood pressure, rapid shallow breathing, rapid heart rate and weak pulse, cold, clammy skin, dizziness, that may lead to collapse (shock).
- Allergic reactions such as skin reactions that may spread throughout the body (rash, redness).
- Pain situated on the nerve route (neuralgia), fits (convulsions), neurological disorders that may result in stiff neck, confusion, numbness, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all of the body (encephalomyelitis, neuritis, Guillain-Barré syndrome).
- Inflammation of the blood vessels (vasculitis) which may result in skin rashes and in very rare cases in temporary kidney problems.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you or your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can report any side effects directly to Sanofi's Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

You can also report side effects via the **Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of this vaccine.

5. How to store VAXIGRIP TETRA

- Store in a refrigerator between 2 °C and 8 °C.
- Do not freeze.
- Shake before use.
- Keep the syringe in the outer carton in order to protect from light.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date indicated on the label or the package.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VAXIGRIP TETRA contains:

The active substances are:

Composition per 0,5 mL dose:

Split influenza virus, inactivated strains for 2023 Southern Hemisphere

A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238)……15 micrograms*

A/Croatia/10136RV/2023 (H3N2)-like strain (A/Croatia/10136RV/2023, X-425A))….15 micrograms*

B/Austria/1359417/2021 – like strain (B/Michigan/01/2021, wild type)…….…….. 15 micrograms*

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

* Haemagglutinin

This vaccine complies with WHO (World Health Organisation) Southern Hemisphere recommendations for the 2025 season.

The other ingredients are a buffered saline solution containing sodium chloride, potassium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate and water for injections.
VAXIGRIP TETRA may contain traces of eggs, such as ovalbumin, and of neomycin, formaldehyde and octoxinol-9, which are used during the manufacturing process.

What VAXIGRIP TETRA looks like and contents of the pack:

Colourless opalescent liquid and free from visible particulate matter, presented in a pre-filled syringe that contains one dose of 0,5 mL.
Type I clear, colourless glass pre-filled syringe with a black bromobutyl or chlorobutyl plunger-stopper without or with a 25 G 5/8 needle.

Holder of Certificate of Registration:

sanofi-aventis south africa (pty) ltd

Hertford Office Park

Building 1, 5th Floor

90 Bekker Road,

Vorna Valley, Midrand, 2196

Tel: 011 256 3700

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