



## I Référence Pantone U : Black



## VAXIGRIP

Suspension for injection in multidose vial

Influenza vaccine (split virion, inactivated)

2019/2020 STRAINS

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

- What VAXIGRIP is and what it is used for
- What you need to know before you or your child use VAXIGRIP
- How to use VAXIGRIP
- Possible side effects
- How to store VAXIGRIP
- Contents of the pack and other information

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

Pharmacotheapeutic group: influenza vaccine - ATC code: J07BB02 VAXIGRIP is a vaccine.

This vaccine, administered to you or your child from 6 months of age, helps to protect you or your child against influenza (flu).

When a person receives the vaccine VAXIGRIP, the immune system (the body's natural defence system) will produce its own protection (antibodies) against the disease.

When administered during pregnancy, the vaccine helps to protect the pregnant woman but also helps to protect her baby(ies) from birth to almost 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 should be used according to official recommendations.

Flu is a disease that can spread rapidly and is caused by different types of virus strains that can change every year. This is why you or your child may need to be vaccinated every year. The greatest risk of catching flu is during the coldest months, between October and March. If you or your child were not vaccinated in the autumn, it is still possible to do it until spring since you or your child run

the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

VAXIGRIP is intended to protect you or your child against the three strains of virus contained in the vaccine after about 2 to 3 weeks following the injection. The incubation period for flu is a few days, so if you or your child are exposed to flu immediately before or after vaccination, you or your child could still develop the illness.

The vaccine will not protect you or your child against the common cold, even though some of the symptoms are similar to flu.

#### 2. What you need to know before you or your child use VAXIGRIP

To make sure that VAXIGRIP is suitable for you or your child, it is important to tell your doctor or pharmacist if any of the points below apply to you or your child.

If there is anything you do not understand, ask your doctor or pharmacist to explain.

#### Do not use VAXIGRIP:

- If you or your child are allergic (hypersensitive) to:
  - the active substances or
  - any of the other ingredients of this vaccine (listed in section 6), or
  - any component that may be present in very small amounts such as eggs (ovalbumin or chicken proteins), neomycin, formaldehyde or octoxinol-9.
- If you or your child have an illness with a high or moderate temperature or an acute illness, the vaccination should be postponed until after you or your child have recovered.

#### Warnings and precautions

Talk to your doctor or your pharmacist before using VAXIGRIP.

You should tell your doctor before vaccination if you or your child:

- have a poor immune response (immunodeficiency or taking medicines affecting the immune system)
- have bleeding problems or bruise easily.

Your doctor will decide if you or your child should be vaccinated.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell your doctor or nurse if you or your child fainted with a previous injection.

If, for any reason, you or your child have to have a blood test within the days following the flu vaccination, please tell your doctor. This is because false positive blood test results have been observed in a few patients who had recently been vaccinated.

As with all vaccines, VAXIGRIP may not fully protect all persons who are vaccinated.

Not all babies less than 6 months of age born to pregnant women vaccinated during pregnancy may be protected.

#### Children

See section "Warnings and precautions".

#### Other medicines and VAXIGRIP

Tell your doctor or pharmacist if you or your child are taking or have recently taken any other vaccines or any other medicines.

- VAXIGRIP can be given at the same time as other vaccines by using separate limbs. In this case, the side effects may be intensified.
- The immunological response may decrease in case of immunosuppressant treatment, such as corticosteroids, cytotoxic drugs or radiotherapy.

#### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant, ask your doctor or pharmacist for advice before using this medicine.

VAXIGRIP can be used in all stages of pregnancy. VAXIGRIP may be used during breast-feeding.

Your doctor or pharmacist will be able to decide if you should receive VAXIGRIP.

#### Driving and using machines

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

#### VAXIGRIP contains potassium and sodium

This medicine contains less than 1 mmol potassium (39 mg) and sodium (23 mg) per dose, i.e. essentially potassium-free\* and sodium-free\*.

#### 3. How to use VAXIGRIP

Adults receive one 0.5 ml dose.

#### Use in children and adolescents

Children aged 36 months and older receive one 0.5 ml dose.

Children aged 6 months to 35 months receive one 0.25 ml dose.

If this is required by national recommendations, a 0.5 ml dose may be given.

If your child is aged less than 9 years and has not been previously vaccinated against flu, a second dose should be given after at least 4 weeks.

If you are pregnant, the 0.5 ml dose administered to you during pregnancy may protect your baby from birth to almost 6 months of age. Ask your doctor or pharmacist for more information.

Your doctor will administer the recommended dose of the vaccine as an injection into the muscle or deep under the skin.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### If you or your child use more VAXIGRIP than you should

In some cases, more than the recommended dose was used.

In these cases, when side effects were reported, the information was in line with what is described in section 4.

#### 4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

#### Allergic reactions

See a doctor **IMMEDIATELY** if you or your child experience 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)

- swelling, most often situated on the head and neck, including the face, lips, tongue, throat or any other part of the body and which may cause difficulty in swallowing or breathing (angioedema).

See a doctor if you or your child experience allergic reactions that may affect:

- the skin: such as itching, hives, rash, redness, areas of itchy, red, swollen, and cracked skin (dermatitis atopic), flushing
- the eyes: such as excess of blood in the white of the eye (ocular hyperaemia), redness and irritation of the eye (conjunctivitis allergic)
- the throat and the nose: such as throat irritation, sore throat, allergic irritation inside the nose, runny nose, sneezing, stuffy nose, sinus or throat
- the mouth: such as numbness or pins and needles sensation (paraesthesia oral), rash (oral mucosal eruption), flushing
- breathing: such as asthma, difficulty breathing (dyspnoea).

These allergic reactions were reported as uncommon (may affect up to 1 in 100 people) to rare (may affect up to 1 in 1,000 people).

#### Other side effects reported

*Very common (may affect more than 1 in 10 people) in adults and elderly*

- Headache
- Muscle pain
- Malaise <sup>(\*)</sup>
- Pain at the injection site

*Common (may affect up to 1 in 10 people) in adults and elderly*

- Shivering, fever <sup>(\*)</sup>
- Reactions at the injection site: redness, hardness, swelling
- Uncommon (may affect up to 1 in 100 people) in adults and elderly*
- Swelling of the glands in the neck, armpit or groin <sup>(\*)</sup>
- Unusual weakness <sup>(\*)</sup>, tiredness, sleepiness <sup>(\*)</sup>, dizziness <sup>(\*)</sup>, increased sweating <sup>(\*)</sup>
- Joint pain <sup>(\*)</sup>
- Feeling sick (nausea), diarrhoea
- Reactions at the injection site: bruising, itching, warmth <sup>(\*)</sup>, discomfort

*Rate (may affect up to 1 in 1,000 people) in adults and elderly*

- Numbness or pins and needles sensation (paraesthesia), decrease sensitivity (hypoesthesia) <sup>(\*)</sup>
- Vomiting, decreased appetite, abdominal pain <sup>(\*)</sup>
- Signs of flu-like illness <sup>(\*)</sup>
- Reactions at the injection site: peeled off skin (exfoliation) <sup>(\*)</sup>, allergy <sup>(\*)</sup>

<sup>(\*)</sup> Less frequent in elderly <sup>(\*)</sup> Less frequent in adults

<sup>(\*)</sup> In adults <sup>(\*)</sup> In elderly

*Very common (may affect more than 1 in 10 people) in children and adolescents from 3 to 17 years of age*

- Headache
- Muscle pain
- Malaise, shivering <sup>(\*)</sup>
- Reactions at the injection site: pain, redness, swelling , hardening <sup>(\*)</sup>

*Common (may affect up to 1 in 10 people) in children and adolescents from 3 to 17 years of age*

- Fever, shivering <sup>(\*)</sup>
- Reactions at the injection site: bruising <sup>(\*)</sup>, hardening <sup>(\*)</sup>

*Uncommon (may affect up to 1 in 100 people) in children and adolescents from 3 to 17 years of age*

- Swelling of the glands in the neck, armpit or groin <sup>(\*)</sup>, unusual weakness <sup>(\*)</sup>, tiredness, dizziness <sup>(\*)</sup>, crying <sup>(\*)</sup>
- Diarrhoea <sup>(\*)</sup>, abdominal pain <sup>(\*)</sup>
- Reactions at the injection site: bruising <sup>(\*)</sup>, itching, warmth <sup>(\*)</sup>, discomfort <sup>(\*)</sup>

*Very common (may affect more than 1 in 10 people) in children from 6 to 35 months of age*

- Headache <sup>(\*)</sup>, unusual crying <sup>(\*)</sup>, irritability <sup>(\*)</sup>, drowsiness <sup>(\*)</sup>
- Muscular pain <sup>(\*)</sup>

- Fever, loss of appetite <sup>(\*)</sup>
- Reactions at the injection site: tenderness, redness, hardness, bruising, swelling

*Common (may affect up to 1 in 10 people) in children from 6 to 35 months of age*

- Vomiting <sup>(\*)</sup>, diarrhoea
- Shivering <sup>(\*)</sup>

<sup>(\*)</sup> In 3 to 8 years old <sup>(\*)</sup> In 9 to 17 years old <sup>(\*)</sup> In 24 to 35 months old

<sup>(\*)</sup> In 6 to 23 months old

*The frequency of the following side effects is not known (cannot be estimated from the available data) in the whole population except in the population for which the side effect is listed above:*

- Swelling of the glands in the neck, armpit or groin
- Numbness or pins and needles sensation (paraesthesia)
- Pain situated on the nerve root (neuralgia)
- 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 the body (encephalomyelitis, neuritis <sup>(\*)</sup>, Guillain-Barré Syndrome <sup>(\*)</sup>)
- Blood vessel inflammation (vasculitis) which may result in skin rashes and in very rare cases in temporary kidney problems
- Temporary reduction in the number of certain blood elements called platelets; a low number of these can result in excessive bruising or bleeding (transient thrombocytopenia).

<sup>(\*)</sup> Not reported in children from 6 to 35 months old

Most side effects usually occurred within the 3 days following vaccination, disappeared within 3 days without treatment. The intensity of these side effects was mild to moderate.

This vaccine contains thiomersal (an organomercuric compound) as a preservative and therefore allergic reactions (hypersensitivity) may occur.

#### Reporting of side effects

If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store VAXIGRIP

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

#### What VAXIGRIP contains

- The active substances are: influenza virus (inactivated by formaldehyde, split by octoxinol-9) of the following strains\*:
  - A/Brisbane/02/2018 (H1N1)pdm09 - like strain
  - A/Kansas/14/2017 (H3N2) - like strain
  - A/Kansas/14/2017 (NYMC X-327) - like strain
  - B/Colorado/06/2017 - like strain
  - B/Maryland/15/2016, NYMC BX-69A) - like strain

\* Propagated in fertilised hens' eggs from healthy chicken flocks

\*\* Haemagglutinin

This vaccine complies with the WHO (World Health Organization recommendations (Northern Hemisphere) and European Union decision for the 2019/2020 season.

The other ingredients are: thiomersal and a buffer solution containing sodium chloride, disodium phosphate d hydrate, potassium dihydrogen phosphate, potassium chloride, water for injections.

This vaccine may contain very small quantities (not more than 7.5 picograms) of neomycin.

#### What VAXIGRIP is and contents of the pack

VAXIGRIP is a suspension for injection in vial of 10 doses of 0.5 ml in box of 1 or 10.

Not all pack sizes may be marketed.

The vaccine, after shaking gently, is a slightly whitish and opalescent liquid.

#### Marketing authorisation holder

**SANOFI PASTEUR** - 14 Espace Henry Vallée - 69007 Lyon - France

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## VAXIGRIP

### Suspensión inyectable en frasco multidosis

### Vacuna antigripal

(inactivada, de virus fraccionados)

CEPAS 2019/2020

Lea todo el prospecto detenidamente antes de que usted o su hijo sean vacunados porque contiene información importante para usted.

- Conserve este prospecto ya que puede tener que volver a leerlo.
- Si tiene alguna duda, consulte a su médico o farmacéutico.
- Esta vacuna se le ha recetado solamente a usted o a su hijo y no debe dárselo a otras personas.
- Si usted o su hijo experimentan efectos adversos, consulte a su médico o farmacéutico incluso si se trata de efectos adversos que no aparecen en este prospecto. Ver sección 4.

#### Contenido del prospecto

- Qué es VAXIGRIP y para qué se utiliza
- Qué necesita saber antes de empezar a usar VAXIGRIP
- Cómo usar VAXIGRIP
- Posibles efectos adversos
- Conservación de VAXIGRIP
- Contenido del envase e información adicional

#### 1. Qué es VAXIGRIP y para qué se utiliza

Grupo farmacoterapéutico: vacuna antigripal – código ATC: J07BB02 VAXIGRIP es una vacuna.

Esta vacuna que se le administra a usted o a su hijo a partir de 6 meses de edad ayuda a protegerle a usted o a su hijo contra la gripe.

Cuando una persona recibe la vacuna VAXIGRIP, el sistema inmunitario (el sistema de las defensas naturales del organismo) produce su propia protección (anticuerpos) contra la enfermedad.

Cuando se administra durante el embarazo, la vacuna ayuda a proteger a la mujer embarazada pero también ayuda a proteger a su hijo(s), desde el nacimiento hasta 6 meses aproximadamente, gracias a la transmisión de la protección de la madre al hijo durante el embarazo (ver igualmente las secciones 2 y 3).

Ninguno de los componentes de la vacuna puede provocar la gripe. VAXIGRIP debe usarse según las recomendaciones oficiales.

La gripe es una enfermedad que puede propagarse rápidamente y que está causada por diferentes cepas de virus que pueden cambiar cada año. Por ello, usted o su hijo pueden necesitar vacunarse cada año. El riesgo más alto de contraer la gripe es durante los meses más fríos, entre octubre y marzo. Si usted o su hijo no han sido vacunados en otoño, todavía es posible hacerlo hasta la primavera, ya que usted o su hijo corren el riesgo de contraer la gripe hasta esta estación. Su médico podrá aconsejarle sobre cuál es el mejor momento para que se vacune.

VAXIGRIP está destinado a proteger a usted o a su hijo contra las tres cepas de virus contenidas en la vacuna después de unas 2 o 3 semanas de la inyección. El período de incubación de la gripe dura unos días. Así, si usted o su hijo han estado expuestos a la gripe justo antes o después de la vacunación, usted o su hijo pueden todavía desarrollarla enfermedad.

La vacuna no protegerá a usted o a su hijo contra los resfriados a pesar de que algunos síntomas se parezcan a los de la gripe.

#### 2. Qué necesita saber antes de empezar a usar VAXIGRIP

Para asegurarse de que VAXIGRIP es apropiado para usted o su hijo, es importante que avise a su médico o farmacéutico si alguno de los puntos siguientes es aplicable a usted o su hijo.

Si no entiende algo, pida a su médico o farmacéutico que se lo explique.

#### No use VAXIGRIP:

- Si usted o su hijo son alérgicos (hipersensibles):
  - a los principios activos o
  - a alguno de los otros componentes de esta vacuna (mencionados en la sección 6), o
  - a cualquier compuesto que pudiera estar presente en cantidades muy pequeñas, como huevo (ovalbumina o proteína de pollo), neomicina, formaldehído u octoxinol-9.

Si usted o su hijo sufren una enfermedad con fiebre alta o moderada, o una enfermedad aguda, la vacunación debe posponerse hasta que se hayan recuperado.

#### Advertencias y precauciones

Consulte a su médico o a su farmacéutico antes de usar VAXIGRIP. Debe informar a su médico antes de la vacunación si usted o su hijo:

- tienen una respuesta inmune baja (immunodeficiencia o toma de medicamentos que afectan al sistema inmunitario).
- sufren trastornos de la coagulación o tienen amaratamientos fácilmente.

Su médico decidirá si usted o su hijo deben recibir la vacuna.

Se pueden producir desmayos (principalmente en los adolescentes) después, o incluso antes, de cualquier inyección con agua. Por eso, informe a su médico o enfermero si usted o su hijo se han desmayado durante una inyección previa.

Si por cualquier razón, se le debe hacer a usted o a su hijo un análisis de sangre en los días siguientes a la vacunación contra la gripe, informe a su médico. En efecto, se han observado análisis con resultados positivos falsos en algunos pacientes que habían sido vacunados recientemente.

Al igual que todas las vacunas, VAXIGRIP puede no proteger completamente a todas las personas vacunadas. Es posible que no todos los niños de menos de 6 meses de edad nacidos de mujeres vacunadas durante el embarazo estén protegidos.

#### Niños

Ver sección "Advertencias y precauciones".

#### Uso de VAXIGRIP con otros medicamentos

Comunique a su médico o farmacéutico si usted o su hijo están tomando o han tomado recientemente otra vacuna u otro medicamento.

- VAXIGRIP puede administrarse al mismo tiempo que otras vacunas pero en extremidades diferentes. En este caso, pueden intensificarse los efectos adversos.
- La respuesta inmunológica puede disminuir en caso de tratamientos inmunosupresores, como corticosteroides, fármacos citotóxicos o radioterapia.

#### Embarazo y lactancia

Si está embarazada o en periodo de lactancia, si cree que podría estar embarazada, consulte a su médico o farmacéutico antes de usar este medicamento.

VAXIGRIP puede usarse en todas las etapas del embarazo. VAXIGRIP puede utilizarse durante la lactancia.

Su médico o farmacéutico será capaz de decidir si debe recibir VAXIGRIP.

#### Conducción y uso de máquinas

La influencia de VAXIGRIP sobre la capacidad para conducir y utilizar máquinas es nula o insignificante.

#### VAXIGRIP contiene potasio y sodio

Este medicamento contiene menos de 1 mmol de potasio (39 mg) y de sodio (23 mg) por dosis, es decir, prácticamente no contiene potasio ni sodio.

#### 3. Cómo usar VAXIGRIP

Los adultos reciben una dosis de 0,5 ml.

#### Uso en niños y los adolescentes

Los niños a partir de 36 meses de edad reciben una dosis de 0,5 ml.

Los niños de 6 a 35 meses de edad reciben una dosis de 0,25 ml. Se puede administrar una dosis de 0,5 ml si las recomendaciones nacionales lo precizan.

Si su hijo tiene menos de 9 años de edad y no ha sido vacunado previamente contra la gripe, debe administrársele una segunda dosis después de un intervalo de al menos 4 semanas.

Si está embarazada, la dosis de 0,5 ml se le administre durante el embarazo puede proteger a su hijo desde el nacimiento hasta casi los 6 meses de edad. Pregunte a su médico o farmacéutico.

Su médico le administrará la dosis recomendada de vacuna con una inyección en el músc