

# VAXIGRIP

Suspension for injection

**2018 STRAINS**

**INFLUENZA VACCINE  
(SPLIT VIRION, INACTIVATED)**

**Read all of this leaflet carefully before you or your child receive this vaccine because it contains important information for you or your child.**

- 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**

1. What VAXIGRIP is and what it is used for
2. What you need to know before you or your child use VAXIGRIP
3. How to use VAXIGRIP
4. Possible side effects
5. How to store VAXIGRIP
6. Further information

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

VAXIGRIP is a vaccine.

This vaccine helps to protect you or your child from 6 months of age against influenza (flu), particularly if you or your child runs a high risk of associated complications.

- Persons aged  $\geq 65$  years.
- Residents of nursing homes and other chronic-care, facilities that house persons of any age who have chronic medical conditions.
- Adults and children who have chronic disorders of the pulmonary or cardiovascular systems, including children with asthma.
- Adults and children who have required regular follow-up or hospitalization during the preceding year because of chronic metabolic diseases including diabetes mellitus, renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications).
- Children and teenagers (aged 6 months - 18 years) who are receiving long-term aspirin therapy and therefore might be at risk for developing Reye syndrome after influenza.
- Subjects who work in public services.
- Medical staff or family members of high-risk subjects.

VAXIGRIP should be used according to official recommendations.

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. None of the ingredients in the vaccine can cause flu.

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. 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 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 problem or bruising easily.

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

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.

### **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 or are planning to have baby, ask your doctor or pharmacist for advice before using this medicine.

Flu vaccines can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of inactivated influenza vaccines do not indicate any adverse foetal and maternal outcomes attributable to the vaccine.

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 or 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**

### **Dosage**

Adults receive one 0.5 ml dose.

#### *Use in children*

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.

### **Method of administration**

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)
- Allergic reactions such as skin reactions that may spread throughout the body including itching, hives, rash, redness (erythema).

These side effects are rare (may affect up to 1 in 1,000 people) except urticaria which is uncommon (may affect up to 1 in 100 people) in children aged 3 years to 8 years. For children aged 6 to 35 months, the frequency of these side effects is not known (cannot be estimated from the available data).

### **Other side effects reported**

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

- Headache<sup>(1)</sup>
- Muscle pain<sup>(1)</sup>
- Malaise<sup>(1) (2)</sup>, unusual tiredness or weakness<sup>(1) (2)</sup>
- Injection site reactions<sup>(1)</sup>: pain, redness, swelling, hardening, itchiness<sup>(2)</sup>

**Very common (may affect more than 1 in 10 people) in pediatric\* population:**

- Headache<sup>(1) (5) (6)</sup>, unusual crying<sup>(1) (4)</sup>, irritability<sup>(1) (4)</sup>, drowsiness<sup>(1) (4)</sup>
- Muscle pain<sup>(1) (5) (6)</sup>
- Diarrhoea<sup>(1) (4)</sup>
- Decrease or loss of appetite<sup>(1) (4)</sup>
- Malaise<sup>(1) (5) (6)</sup>, fever<sup>(1) (4)</sup>, shivering<sup>(1) (6)</sup>
- Injection site reactions<sup>(1)</sup>: pain, redness, swelling, hardening<sup>(4) (5)</sup>

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

- Joint pain<sup>(1)</sup>
- Increased sweating<sup>(1)</sup>
- Injection site reactions: bruising<sup>(1)</sup>, itchiness<sup>(3)</sup>
- Shivering<sup>(1)</sup>, fever<sup>(1)</sup>, malaise<sup>(3)</sup>, unusual tiredness or weakness<sup>(3)</sup>

**Common (may affect up to 1 in 10 people) in pediatric\* population:**

- Dizziness<sup>(6)</sup>
- Insomnia<sup>(1) (4)</sup>
- Vomiting<sup>(1) (4)</sup>
- Fever<sup>(5) (6)</sup>, shivering<sup>(5)</sup>
- Injection site reactions: bruising<sup>(1)</sup>, itchiness, discomfort<sup>(6)</sup>, hardening<sup>(6)</sup>, warmth<sup>(6)</sup>

**Uncommon (may affect up to 1 in 100 people) in adults and elderly:**

- Swelling of the glands in the neck, armpit or groin<sup>(2)</sup>
- Sleepiness<sup>(3)</sup>, dizziness<sup>(3)</sup>
- Nausea<sup>(2)</sup>, diarrhoea<sup>(1)</sup>
- Flu-like syndrome<sup>(2)</sup>
- Injection site reactions<sup>(2)</sup>: discomfort, warmth

**Uncommon (may affect up to 1 in 100 people) in pediatric\* population:**

- Swelling of the glands in the neck, armpit or groin<sup>(5)</sup>

- Diarrhoea<sup>(5)</sup>
- Injection site reactions<sup>(5)</sup>: haemorrhage, warmth

\* Children/adolescents aged 6 months to 17 years

Rare (may affect up to 1 in 1000 people) in adults and elderly:

- Numbness or pins and needles sensation (paraesthesia), decrease of sensitivity (hypoesthesia)<sup>(2)</sup>, numbness, pain and weakness of the arm (brachial radiculitis)<sup>(3)</sup>, pain situated on the nerve route (neuralgia)<sup>(3)</sup>
- Swelling of the glands in the neck, armpit or groin<sup>(3)</sup>

Not known frequency (frequency cannot be estimated from the available data)

- Swelling of the glands in the neck, armpit or groin (lymphadenopathy)<sup>(4) (6)</sup>
- Numbness or pins and needles sensation (paraesthesia)<sup>(7)</sup>
- Pain situated on the nerve route (neuralgia)<sup>(5) (6)</sup>
- 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>(2) (3) (5) (6)</sup>, Guillain-Barré Syndrome<sup>(2) (3) (5) (6)</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>(1)</sup> These side effects usually occurred within the 3 days following vaccination and disappeared within 1 to 3 days without treatment. Most of these side effects were of mild to moderate intensity. <sup>(2)</sup> In adults <sup>(3)</sup> In the elderly <sup>(4)</sup> 6 to 35 months old <sup>(5)</sup> 3 to 8 years old <sup>(6)</sup> 9 to 17 years old <sup>(7)</sup> 6 months to 17 years old

**For multidose presentation:** 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 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 syringe 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. Further information

### What VAXIGRIP contains

**The active substances are:** Influenza virus (inactivated, split) of the following strains\*:

A/Michigan/45/2015 (H1N1)pdm09 – like strain (A/Michigan/45/2015, NYMC X-275)	15 micrograms HA**
A/Singapore/INFIMH-16-0019/2016 (H3N2) – like strain (A/Singapore/INFIMH-16-0019/2016, NIB-104)	15 micrograms HA**
B/PHUKET/3073/2013 – like strain (B/PHUKET/3073/2013, wild type)	15 micrograms HA**

Per 0.5-ml dose

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

\*\* Haemagglutinin

This vaccine complies with the WHO (World Health Organization) recommendations (Southern hemisphere) for the 2018 season.

**The other ingredients are:** thiomersal (in multidose vials only) and a buffer solution containing sodium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate, potassium chloride, water for injections.

### What VAXIGRIP looks like and contents of the pack

VAXIGRIP is a suspension for injection in a prefilled syringe of 0.25 or 0.5 ml in box of 1, 10 or 20, in vial containing 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 SA** - 2, Avenue Pont Pasteur - 69007 Lyon - France

**This leaflet was last revised in: 10/2017.**

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### The following information is intended for healthcare professionals only:

As with all injectable vaccines, appropriate medical treatment and supervision should be readily available in case of an anaphylactic reaction, although rare, following the administration of the vaccine.

The vaccine should be brought to room temperature before use.

Shake before use.

The vaccine should not be used if foreign particles are present in the suspension.

It should not be mixed with other medicinal products in the same syringe.

This vaccine is not to be injected directly into a blood vessel.

### Instructions for the administration of dose of 0.25 ml in children aged 6 to 35 months

When one dose of 0.25 ml is indicated and if VAXIGRIP 0.5 ml presentation is used, in order to eliminate half of the volume of the 0.5 ml syringe: the syringe should be held in an upright

position and the plunger stopper should be pushed until it reaches the fine black line printed on the syringe. The remaining volume of 0.25 ml should be injected.

See also Section 3. How to use VAXIGRIP.

**or multidose vial:**

Any opened multidose vial remaining after a vaccination session should be discarded in accordance with WHO recommendations (1).

For each dose taken and for each patient, a new sterile syringe fitted with a new sterile needle is used.

Between different removals and in any case within 5 minutes maximum after removal of the last dose, the vial should be placed back in the refrigerator to keep the product at the required temperature, i.e. between 2°C and 8°C (never in the freezer).

In any case, when in storage period, the vial should be stored according to the conditions described in the manufacturer's instructions for use.

See also section 3. HOW TO USE VAXIGRIP

(1) After removal of the first dose, the vaccine contained in the vial must imperatively be used within 7 days.

A partially used vial must be destroyed immediately if:

- Sterile removal has not been strictly carried out,
- There is any suspicion that a partially used vial has been contaminated,
- There is visible sign of contamination, such as change in the appearance or the presence of particles in suspension.

For multidose presentations when a Vaccine Vial Monitor (VVM) is on the cap

The Vaccine Vial Monitors (VVM) are on the cap of VAXIGRIP vaccine supplied through SANOFI PASTEUR. The colour dot which appears on the cap of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond and acceptable level.



- ✓ Inner square lighter than outer circle. **If the expiry date has not been passed, USE the vaccine.**



- ✗ **Discard point:** inner square matches colour of outer circle. **DO NOT USE the vaccine.**



- ✗ **Beyond the discard point:** inner square darker than outer circle. **DO NOT USE the vaccine.**

The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the circle, then the vaccine can be used. As soon as the colour of the central square is the same colour as the circle or of a darker colour than the circle, then the vial should be discarded.