

# VAXIGRIP<sup>®</sup>, VAXIGRIP<sup>®</sup> Junior

## *Influenza Vaccine (split virion, inactivated)*

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### Consumer Medicine Information

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#### What Is In This Leaflet

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This leaflet answers some common questions about VAXIGRIP<sup>®</sup> and VAXIGRIP<sup>®</sup> Junior.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you or your child having VAXIGRIP<sup>®</sup> or VAXIGRIP<sup>®</sup> Junior against the benefits they expect they will have.

**If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.**

**Keep this leaflet.**

You may need to read it again.

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#### What VAXIGRIP<sup>®</sup> and VAXIGRIP<sup>®</sup> Junior are Used For

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VAXIGRIP<sup>®</sup> and VAXIGRIP<sup>®</sup> Junior are vaccines used to help prevent influenza ('flu'), especially in people who have a high risk of getting complications. VAXIGRIP<sup>®</sup>

Junior is for use in children aged 6 to 35 months.

New types of influenza virus can appear each year hence vaccination against flu is recommended every year for anyone who wishes to reduce their chance of becoming ill with flu.

Annual vaccination against flu is particularly recommended for the following people:

- Everyone over 65
- Aboriginal and Torres Strait Islanders 15 years and over
- Anyone aged 6 months or older with chronic conditions especially heart, lung, kidney or nervous system disorders, diabetes and immune problems, including HIV
- Children (6 months to 10 years) on long-term aspirin therapy
- Women planning to become pregnant or pregnant women who will be in the 2nd or 3rd trimester of pregnancy during the flu season
- People in nursing homes or other long term care facilities
- Close contacts of anyone who is at risk of getting complications from flu
- People in the workforce, especially

those working in health care and other essential community services

- Travellers

Vaccination against flu is important in these people because they risk getting severe flu or other complications, and because they may help to spread flu to other people 'at risk'.

#### **How They Work**

VAXIGRIP<sup>®</sup> and VAXIGRIP<sup>®</sup> Junior work by helping the body to make its own protection against the infection caused by influenza virus types A and B.

After receiving VAXIGRIP<sup>®</sup> or VAXIGRIP<sup>®</sup> Junior injection, the body will start making antibodies. These antibodies help the body to recognise the virus and prevent the infection. It takes about 2 to 3 weeks for the body to produce these antibodies, and in most cases, these antibodies will protect you or your child for 6 to 12 months. The vaccine will only protect you against the three types of influenza virus contained in the vaccine. It will not protect you from influenza caused by other types of viruses.

Protection requires 1 to 2 doses.

Most people will produce enough antibodies against influenza. However, as with all vaccines, 100% protection cannot be guaranteed.

The virus in the vaccine is killed. Therefore the vaccine will not give you or your child the flu.

The chance of a severe reaction from VAXIGRIP® or VAXIGRIP® Junior is very small, but the risks of not being vaccinated against the flu may be very serious.

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## **Before Receiving VAXIGRIP® or VAXIGRIP® Junior**

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### ***When You or Your Child Must Not Be Given It***

**Do not have VAXIGRIP® or VAXIGRIP® Junior if you or your child has an allergy to:**

- VAXIGRIP®, VAXIGRIP® Junior or any of the ingredients listed at the end of this leaflet
- Eggs or egg products, or chicken proteins
- Neomycin (an antibiotic)

Symptoms of an allergic reaction may include:

- Shortness of breath, wheezing or difficulty breathing;
- Swelling of the face, lips, tongue or other parts of the body;
- Skin rash, itching or hives

**Do not have VAXIGRIP® or VAXIGRIP® Junior if you or your child has an illness with a high temperature.**

**VAXIGRIP® and VAXIGRIP® Junior are not recommended for use in infants under 6 months of age.**

**Do not have VAXIGRIP® or VAXIGRIP® Junior after the expiry date printed on the pack.**

**Do not have VAXIGRIP® or VAXIGRIP® Junior if the packaging is torn or shows signs of tampering.**

**If you are not sure whether you or your child should have VAXIGRIP® or VAXIGRIP® Junior, talk to your doctor or pharmacist.**

### ***Before You or Your Child Is Given It***

**Tell your doctor if you or your child has ever had a severe allergic reaction to a vaccine.**

**Tell your doctor if you or your child has an infection or high temperature.**

Your doctor may decide to delay vaccination until the illness has passed. A mild illness, such as a cold, is not usually a reason to delay vaccination.

**Tell your doctor if you or your child has, or has had, any medical**

**conditions, especially the following:**

- Weakened immunity due to disease such as some blood disorders, leukaemia, malaria, kidney disease requiring dialysis, HIV/AIDS or cancer
- Weakened immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer
- Guillain-Barré Syndrome

**Tell your doctor if you or your child has allergies to:**

- Any other medicines
- Any other substances such as foods, preservatives or dyes

**Speak to your doctor before you have VAXIGRIP® if you are pregnant or intend to become pregnant.**

Your doctor will discuss the possible risks and benefits of having VAXIGRIP® during pregnancy.

**Tell your doctor if you are breast-feeding:**

Your doctor will discuss the possible risks and benefits of vaccination; however, the vaccine is not expected to cause any problems for breast-fed babies.

### ***Taking Other Medicines***

**Tell your doctor or pharmacist if you or your child is taking any other medicines, including any that you buy without a**

**prescription from your pharmacy, supermarket or health food shop.**

Some medicines and VAXIGRIP® or VAXIGRIP® Junior may interfere with each other. These include:

- Phenytoin, phenobarbitone or carbamazepine, medicines used to control epilepsy or convulsions
- Theophylline, a medicine used to control asthma
- Warfarin, a medicine used to prevent blood clots
- Immunoglobulins, which are blood products used to prevent some infections
- Medicines which lower the immune system, such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)

These medicines may be affected by VAXIGRIP® or VAXIGRIP® Junior, or may affect how well they work. (You may need different amounts of these medicines, or you may need to take different medicines.) Your doctor or pharmacist will advise you and decide whether or not to give the vaccine.

***Having Other Vaccines***

VAXIGRIP® and VAXIGRIP® Junior may be given at the same time as pneumococcal vaccine and all of the vaccines scheduled for use in children.

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**How VAXIGRIP® and VAXIGRIP® Junior are Given**

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VAXIGRIP® and VAXIGRIP® Junior are given as an injection, usually into muscle or tissue below the skin of upper arm (adults and children) or leg (infants and young children).

VAXIGRIP® and VAXIGRIP® Junior should not be injected directly into the veins.

***How Much Is Given***

- Adults and children over 35 months: A single injection (0.5 mL)
- Children 6 to 35 months: A single injection (0.25 mL)

Some children require a second injection a month later.

Please ask your doctor if this includes your child.

***When It Is Given***

VAXIGRIP® and VAXIGRIP® Junior should be given annually.

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**After Having VAXIGRIP® or VAXIGRIP® Junior**

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***Things You Or Your Child Must Do***

**Keep an updated record of your vaccinations.**

***Things to Be Careful Of***

**Be careful driving or operating machinery until you know how VAXIGRIP® affects you.** VAXIGRIP® should not normally interfere with your ability to drive or operate machinery.

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**Side Effects**

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**Do not be alarmed by this list of possible side effects.**

You or your child may not experience any of them.

**Tell your doctor or pharmacist as soon as possible if you or your child does not feel well after having VAXIGRIP® or VAXIGRIP® Junior.**

VAXIGRIP® and VAXIGRIP® Junior may have unwanted side effects in a few people. All medicines, including vaccines, can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- Local reactions around the injection site such as redness, swelling, itchiness, pain or discomfort, bruising, or the formation of hard lumps

- Headaches
- Increased sweating
- Muscle or joint pain
- Fever
- Shivering
- Fatigue or generally feeling unwell

These side effects are usually common and mild and usually disappear within 1-2 days without treatment.

**Tell your doctor immediately if you notice any of the following:**

- Unusual bleeding, bruising or purple spots on the skin
- Painful, swollen joints
- Swelling of the glands in the neck, armpit or groin
- Tingling of the hands or feet, or sudden numbness or weakness in the legs or arms

These may be serious side effects. You or your child may need urgent medical attention. Serious side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- Sudden skin reactions such as rash, itching or hives
- Swelling of the head or neck, including face, lips, tongue or other parts of the body
- Shortness of breath, wheezing or difficulty breathing
- Rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting (shock)

- Headache and fever with hallucinations, confusion, paralysis anywhere on body, disturbances of behaviour, speech and eye movements, stiff neck, and loss of balance or reflexes
- A seizure or convulsion
- Nerve pain, weakness or paralysis in the limbs, often moving to chest and face

These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

**Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you or your child feel unwell.**

**Storing VAXIGRIP® and VAXIGRIP® Junior**

VAXIGRIP® and VAXIGRIP® Junior are usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store VAXIGRIP® or VAXIGRIP® Junior:

- **Keep it where children cannot reach.**
- **Keep it in the original pack until it is time for it to be given.**
- **Keep it in the refrigerator, between 2°C and 8°C. Do not freeze. Protect from light.**

Freezing destroys the vaccine.

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## Product Description

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### **What It Looks Like**

VAXIGRIP® is 0.5 mL of liquid vaccine in a single dose syringe.

VAXIGRIP® Junior is 0.25 mL of liquid vaccine in a single dose syringe.

### **Ingredients**

#### **Active ingredients:**

VAXIGRIP® and VAXIGRIP® Junior have been prepared on eggs and are made from inactivated parts of the following influenza virus strains:

- A/California/7/2009 NYMC X-179A (A/California/7/2009 [H1N1] - like),
- A/Wisconsin/15/2009 NYMC X-183 (A/Perth/16/2009 [H3N2] – like),
- B/Brisbane/60/2008 (B/Brisbane/60/2008 - like)

#### **Other ingredients:**

Buffered saline solution composed of:

- Sodium chloride
- Potassium chloride
- Sodium phosphate (dibasic dihydrate)
- Potassium phosphate (monobasic)
- Water for injection

VAXIGRIP® and VAXIGRIP® Junior may also contain traces of egg proteins, formaldehyde, octoxinol 9 and neomycin.

VAXIGRIP® and VAXIGRIP® Junior do not contain lactose, gluten,

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tartrazine or any other azo dyes.

***Manufacturer***

**Sanofi Pasteur SA**  
Lyon, France

***Distributor***

Australia:

**Sanofi Pasteur Pty Ltd**  
ABN 79 085 258 797  
Talavera Corporate Centre  
– Building D  
12 – 24 Talavera Road  
Macquarie Park  
NSW 2113  
Australia  
Tel: 1800 829 468

***Aust R Number***

Aust R 80198  
(VAXIGRIP<sup>®</sup>)

Aust R 97971  
(VAXIGRIP<sup>®</sup> Junior)

***Date of Preparation***

11 November 2009