

VAXIGRIP®

Inactivated Influenza Vaccine (Split Virion) BP

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VAXIGRIP. 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 against the benefits they expect it 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.

What VAXIGRIP is used for

VAXIGRIP is a vaccine used to help prevent influenza ('flu') especially in people who have a high risk of getting complications. New types of influenza virus can appear each year hence vaccination is recommended every year for anyone who wishes to reduce their chance of becoming ill with the flu.

Annual vaccination against influenza is particularly recommended for the following individuals:

1. All people over the age of 65 years
2. People under 65 years of age with:
 - Heart disease
 - Lung disease - asthma that require regular preventative therapy; other chronic lung disease with impaired lung function
 - Diabetes
 - Kidney disorder
 - Cancer
 - Other conditions – diseases that require treatment with medicines that reduce natural immunity, HIV, children on long-term aspirin therapy
3. Pregnant women

Influenza vaccination is recommended for any pregnant women who are beyond the first trimester of pregnancy i.e. those who will be in the second or third trimester of pregnancy during the influenza season. Influenza vaccination is funded by the government for those pregnant women with a medical condition listed above.

4. Other people

Healthy individuals should consider the use of the vaccine, especially if they are in close contact with individuals at high risk of complications i.e. those who work in medical or health services and those who can transmit influenza to persons in any of the previously mentioned at risk groups.

Employers should consider providing influenza vaccine to avoid illness in their employees, especially those engaged in health care and other essential community services.

How VAXIGRIP works

VAXIGRIP works by helping the body to make its own protection against the infection caused by influenza virus Types A and B. After receiving VAXIGRIP 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 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 is very small, but the risks from not being vaccinated against influenza may be very serious.

Before you are given VAXIGRIP

When you or your child must not be given it

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

- VAXIGRIP 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 reactions 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 if you or your child has an illness with a high temperature.

VAXIGRIP is not recommended for use in infants under 6 months of age.

Do not have VAXIGRIP after the expiry date printed on the pack.

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

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.

If you are not sure whether you or your child should have VAXIGRIP, 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 diseases 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-Barre Syndrome

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

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

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 may interfere with each other. These include:

- Phenytoin, phenobarbitone, carbamazepine, medicines used to control epilepsy or convulsions
- Theophylline, a medicine used to control asthma
- Warfarin, a medicine used to prevent blood clots
- Immunoglobulins, 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 may affect how well it works. (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 may be given at the same time as pneumococcal vaccine and all of the scheduled childhood vaccines.

How VAXIGRIP is given

VAXIGRIP is 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 should not be injected directly into the veins.

How much is given

Adults and children over 35 months: A single injection (0.5mL)

Children 6 months to 35 months: A single injection (0.25mL)

Some children require a second injection a month later. Please ask your doctor if this includes your child.

When it is given

VAXIGRIP should be given annually.

After having VAXIGRIP

Things you or your child must do

Keep an updated record of your vaccination.

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.

Side Effects

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.

VAXIGRIP 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 the body, disturbances of behaviour, speech and eye movements, stiff neck, and loss of balance or reflexes
- A seizure or convulsion (including seizure or convulsion due to fever)
- 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

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

- **Keep it where children cannot reach it**

- **Keep VAXIGRIP 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 VAXIGRIP. Protect from light.**
Freezing destroys the vaccine

Product Description

What it looks like

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

Ingredients

Active Ingredients:

VAXIGRIP 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/Victoria/210/2009 NYMC X-187 (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 may also contain traces of egg proteins, formaldehyde, octoxinol-9 and neomycin.

VAXIGRIP do not contain lactose, gluten, tartrazine or any other azo dyes.

Manufacturer

Sanofi Pasteur SA

Lyon, France

Distributor

New Zealand

sanofi-aventis new zealand limited

Level 8, James & Wells Tower

56 Cawley St

Ellerslie

Auckland

New Zealand

Tel: 0800 727 838

Date of preparation

25 November 2011