VAXIGRIP®
INFLUENZA VACCINE
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. Annual vaccination against influenza is recommended for the following individuals:
– Adults over 65 years of age;
– Aboriginal and Torres Strait Islander adults ≥ 50 years;
– Adults and children 6 months or older with chronic illness, especially chronic heart, lung or kidney disorder or diabetes and others requiring regular medical follow up or hospitalisation in the preceding year;
– Children and teenagers (6 months to 18 years) on long-term aspirin therapy;
– People living in nursing homes and other long term care facilities;
– People receiving medicines that reduce natural immunity;
– Adults and children 6 months or over who can transmit influenza to persons in any of the previously mentioned at risk groups. This includes people who work in medical or health services;
– Persons infected with HIV.
Vaccination against influenza is also recommended for the following persons:
– Pregnant women who are at increased risk or in advance for all women who will be in the 2nd or 3rd trimester of pregnancy during the influenza season;
– Travellers particularly those in large tourist groups or travelling to the Northern Hemisphere from October to March.
Vaccination against influenza is important in these people because they are at risk of severe influenza and more severe secondary consequences, or because they may contribute to the spread of influenza to persons with these risks.

HOW IT WORKS
VAXIGRIP® works by causing your body to produce its own protection against influenza. VAXIGRIP® is used for the prevention of influenza caused by Influenza Virus types A and B. After receiving your VAXIGRIP® injection, your body will
produce antibodies. These antibodies help your body to recognise the virus and prevent the infection. It takes about 2 to 3 weeks for your body to produce these antibodies, and in most cases these antibodies will provide protection for 1 year. Please note that VAXIGRIP® 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 dose. (A second dose may also be required.) Most people will produce enough antibodies against influenza. However, as with all vaccines, 100% protection cannot be guaranteed. The vaccine will not give you or your child influenza. 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, fowl proteins, and/or chicken feathers;
– Neomycin.
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® if you or your child has a high temperature (current acute feverish illness).
Speak to your doctor before you have VAXIGRIP® if you are pregnant or intend to become pregnant because the risk to the foetus or baby is not well known. VAXIGRIP® is not recommended for use in infants under 6 months.
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.
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 reacted to previous vaccination with any of the following:
– Life-threatening allergic reaction;
– Difficulty breathing;
– Swelling of the throat;
– Fainting or collapse;
– Shock-like state or being unresponsive for a long period of time;
– Fits or convulsions;
– High temperature (greater than 40°C);
– Crying or screaming lasting for more than 3 hours;
– Severe skin reaction at the injection site, including severe bruising.

**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:**
– Lowered immunity due to diseases such as some blood disorders, malaria, kidney disease requiring dialysis, HIV/AIDS or cancer;
– Lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer;
– Leukaemia or any other cancers of the blood, bone marrow or lymph system;
– Lung infections or asthma;
– Brain disease;
– Epilepsy;
– Fits or convulsions;
– Allergies or allergic reactions, including: runny, blocked or itchy nose; itchy rash or hives; swelling of the face, lips, mouth or tongue;
– 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.

VAXIGRIP® 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® 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, 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**
**Tell your doctor if you or your child has had any vaccines in the last 4 weeks.**
Your doctor will advise you if VAXIGRIP® is to be given with another vaccine.
Your doctor and pharmacist may have more information on medicines and vaccines to be careful with or avoid during vaccination with VAXIGRIP®.

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

HOW VAXIGRIP® IS GIVEN
VAXIGRIP® is given as an injection, usually into muscle or tissue below the skin of your upper arm or leg although your doctor may choose to give it elsewhere. VAXIGRIP® should not be injected directly into the veins.

HOW MUCH IS GIVEN
– Adults and children 3 years of age and over; a single injection (0.5 mL)
– Infants and children 6 months to 35 months; half of the adult dose (0.25 mL)

Some people require a second injection of VAXIGRIP® a month later. Please ask your doctor if this includes you or 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 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.

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 reaction around the injection site such as redness, itchiness, tenderness, pain or discomfort, warmth, burning or stinging, bruising, swelling or the formation of hard lumps or scars;
– Flushing or redness of the skin;
– Headaches;
– Tiredness, weakness or fatigue, generally feeling unwell;
– Fever;
– Shivering;
– Increased sweating, soreness, aching muscles, muscle tenderness or weakness (not caused by exercise);
– Soreness of the joints.
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:
– Abscess at the injection site;
– Unusual bleeding, bruising or purple spots on the skin;
– Skin rash, itchy spots or red lumps on the skin;
– Painful, swollen joints;
– Swelling of the glands in the neck, armpit or groin;
– Itchiness, hives or rash over the body;
– Fits or convulsions;
– Weak and stiff neck;
– Sore throat, difficulty swallowing;
– 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 signs of allergy such as rash, itching or hives on the skin, shortness of breath, swelling of the face, lips, tongue or other parts of the body;
– Pinkish, itchy swellings on the skin, also called hives or nettle rash;
– A seizure or convulsion, which may be accompanied by a very high temperature;
– Feeling weak or paralysed, or generally feeling sore or tender;
– Rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting (shock);
– Sudden dimming or loss of vision;
– Headache and high temperature associated with hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, stiff neck, and sensitivity to light.
These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.
All of these side effects are 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® is made from inactivated parts of the following Influenza strains:
– A/New Caledonia/20/99 (H1N1) like strain 15 microgram haemagglutinin
– A/Wisconsin/67/2005 (H3N2) like strain 15 microgram haemagglutinin
– B/Malaysia/2506/2004 like strain 15 microgram haemagglutinin
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 formaldehyde, octoxynol-9 and neomycin. VAXIGRIP® does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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