VAXIGRIP®; VAXIGRIP®
Junior

Inactivated Influenza Vaccine (split virion)

Consumer Medicine Information

What is in this leaflet

Read all of this leaflet carefully before you or your child is vaccinated.

• 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. Do not pass it on to others.
• If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
• What VAXIGRIP/VAXIGRIP Junior are and what they are used for
• Before you or your child is given VAXIGRIP/VAXIGRIP Junior
• How VAXIGRIP/VAXIGRIP Junior is given
• Possible side effects
• Storing VAXIGRIP/VAXIGRIP Junior
• Further Information

What VAXIGRIP/VAXIGRIP Junior are and what they are used for

VAXIGRIP and VAXIGRIP Junior are vaccines.

These vaccines help to protect you or your child against influenza (flu), particularly if you or your child runs a high risk of associated complications. VAXIGRIP/VAXIGRIP Junior should be used according to official recommendations.

When a person is given VAXIGRIP/VAXIGRIP Junior, 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 cold months. If you or your child was not vaccinated in the autumn, it is still possible to do it until spring since you or your child runs the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

VAXIGRIP/VAXIGRIP Junior will 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 is exposed to flu immediately before or after your 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.

Before you or your child is given VAXIGRIP/VAXIGRIP Junior

When You or Your Child Must Not Be Given It

Do not have VAXIGRIP/VAXIGRIP Junior:
• If you or your child is allergic (hypersensitive) to:
  • The active substances or
  • Any of the other ingredients of VAXIGRIP/VAXIGRIP Junior, see "Further information" or
  • Any component that may be present in very small amounts such as eggs (egg proteins or chicken proteins), neomycin, formaldehyde or octoxinol-9.
• If you or your child has an illness with a high temperature or acute infection, the vaccination should be postponed until after you or your child has recovered.

Take special care with VAXIGRIP/VAXIGRIP Junior

• You should tell your doctor before vaccination if you or your child has or has had Guillain-Barré Syndrome (severe muscle weakness) after getting a flu vaccine.
• You should tell your doctor before vaccination if you or your child has a poor immune response (immunodeficiency or taking
medicines affecting the immune system).

• Your doctor will decide if you or your child should receive the vaccine.

• If, for any reason, you or your child has 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/VAXIGRIP Junior may not fully protect all persons who are vaccinated.

Pregnancy and breastfeeding

Tell your doctor or pharmacist if you are pregnant or think you may be pregnant.

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 fetal and maternal outcomes attributable to the vaccine.

VAXIGRIP may be used during breastfeeding.

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

Taking Other Medicines

Please tell your doctor or pharmacist if you or your child is taking or has recently taken any other vaccines or any other medicines, including medicines obtained without a prescription.

VAXIGRIP/VAXIGRIP Junior 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.

Having Other Vaccines

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

How VAXIGRIP/VAXIGRIP Junior is given

VAXIGRIP/VAXIGRIP Junior 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/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/VAXIGRIP Junior should be given annually.

Possible Side effects

Like all medicines, VAXIGRIP/VAXIGRIP Junior can cause side effects, although not everybody gets them.

During clinical trials, the following side effects have been observed. Their frequencies have been estimated as Common: affects 1 to 10 users in 100:

• headache,
• sweating,
• muscular pain (myalgia), joint pain (arthralgia),
• fever, generally feeling unwell (malaise), shivering, fatigue,
• local reactions: redness, swelling, pain, bruising, hardness around the area where the vaccine is injected.

These reactions usually disappear within 1-2 days without treatment.

In addition to the common side effects listed above, the following side effects occurred after the vaccine came on the market:

• allergic reactions:
  • leading to medical emergency with a failure of the circulatory system to maintain adequate blood flow to the different organs (shock) in rare cases,
  • swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body (angioedema) in very rare cases,
  • skin reactions that may spread throughout the body including itchiness of the skin (pruritus, urticaria), rash,
  • blood vessel inflammation which may result in skin rashes (vasculitis) and in very rare cases temporary kidney problems,
  • pain situated on the nerve route (neuralgia), anomalies in the perception of touch, pain, heat and cold (paraesthesia), fits (convulsions) associated with fever, 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, Guillain-Barré Syndrome),
  • temporary reduction in the number of certain types of particles in the blood called
platelets; a low number of these can result in excessive bruising or bleeding (transient thrombocytopenia), temporary swelling of the glands in the neck, armpit or groin (transient lymphadenopathy).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Storing VAXIGRIP/VAXIGRIP Junior

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

Further Information

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/VAXIGRIP Junior has been prepared on eggs and is made from inactivated parts of the following influenza virus strains:

- A/South Australia/55/2014 IVR-175 (A/Switzerland/9715293/2013 [H3N2]-like),
- B/Phuket/3073/2013

Other ingredients:

Buffered saline solution composed of:

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

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

VAXIGRIP/VAXIGRIP Junior does not contain lactose, gluten, tartrazine or any other azo dyes.

Name and Address of Australian Sponsor

Australia:

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