

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 or moderate 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).
- You should tell your doctor before vaccination if you or your child has bleeding problems or bruise easily.

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 breast-feeding

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 breast-feeding.

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.

Allergic reactions

See a doctor IMMEDIATELY if you or your child experiences:

– 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

Other side effects reported

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

- Headache (1)
- Muscle pain (1)
- Malaise (1) (2), unusual tiredness or weakness (1) (2)

- Injection site reactions (1): pain, redness, swelling, hardening, itchiness (2)

Very common (may affect more than 1 in 10 people) in paediatric* population

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

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

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

Common (may affect up to 1 in 10 people) in paediatric* population

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

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

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

Uncommon (may affect up to 1 in 100 people) in paediatric* population

- Swelling of the glands in the neck, armpit or groin (5)
- Diarrhoea (5)
- Injection site reactions (5): 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) (2), numbness, pain and weakness of the arm (brachial radiculitis) (3), pain situated on the nerve route (neuralgia) (3)
- Swelling of the glands in the neck, armpit or groin (3)

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

- Swelling of the glands in the neck, armpit or groin (4) (6)
- Numbness or pins and needles sensation (paraesthesia) (7)
- Pain situated on the nerve route (neuralgia) (5) (6)
- 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) (2) (3) (5) (6), Guillain-Barré Syndrome (2) (3) (5) (6))

- 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).
- (1) 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.

(2) In adults

(3) In the elderly

(4) 6 to 35 months old

(5) 3 to 8 years old

(6) 9 to 17 years old

(7) 6 months to 17 years old

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/California/7/2009 NYMC X-179A (A/California/7/2009 [H1N1]pdm09 - like),
- 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:

sanofi-aventis australia Pty Ltd
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Aust R 80198 (VAXIGRIP)

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