# AGRIPPAL® 2015

*Inactivated Influenza Vaccine (surface antigen)*

**Consumer Medicine Information**

## What is in this leaflet

This leaflet answers some common questions about Agrippal vaccine.

It does not contain all the available information.

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

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

**You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the vaccine. You can also download the most up to date leaflet from www.novartis.com.au.**
Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines, including vaccines, have risks and benefits. Your doctor considers the risks of you or your child having Agrippal vaccine and the benefits he/she 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 Agrippal vaccine is used for

Agrippal vaccine helps prevent influenza, often called the flu. Influenza is caused by infection with specific influenza viruses. New types of influenza virus can appear each year. Agrippal vaccine contains strains of three different types of influenza virus. Each year the Australian Influenza Vaccine Committee and the New Zealand Ministry of Health decide which three types of virus are most suitable.

Vaccination against influenza helps prevent infection with influenza and to control the spread of the disease.

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

Note: the vaccine will not protect you or your child from the other influenza viruses that Agrippal vaccine does not contain. It will not protect you from other types of influenza virus or from infections with other agents causing flu-like symptoms (such as the common cold).

Agrippal vaccine is available only with a doctor's prescription. This year (2015) the viruses are:

- A/California/7/2009 (H1N1) - like strain;
- A/Switzerland/9715293/2013 (H3N2)-like strain;
- B/Phuket/3073/2013-like strain.

As influenza viruses can change from year to year, Agrippal is changed to contain strains of the new types of virus. Therefore vaccination against influenza is recommended every year, for anyone wanting to lower their chance of catching influenza.

### *How Agrippal vaccine works*

Agrippal vaccine works by causing your body to protect itself against infection by the influenza viruses, types A and B, that are used to make the vaccine. The body makes substances, called antibodies. Antibodies fight the influenza virus. If you have been vaccinated, when you come into contact with the same types of influenza viruses (inactivated) used to make the vaccine, your body is usually able quickly to destroy the virus. This prevents you from getting influenza.

Your body takes a few weeks after vaccination to fully develop protection against the influenza virus.

Protection against influenza requires one dose of Agrippal vaccine. Sometimes, a follow up (booster) dose may also be given. Your doctor will tell you if you or your child needs another dose.

Most people make satisfactory antibodies against the influenza virus. However, as with all vaccines, 100% protection cannot be guaranteed.

## Before you are given Agrippal vaccine

### *When you or your child must not be given Agrippal vaccine*

**Do not have Agrippal vaccine if you or your child have or previously had an allergy to:**

- any influenza vaccine or any of the ingredients listed at the end of this leaflet;
- eggs and/or chicken proteins, such as ovalbumin;
- the antibiotics kanamycin or neomycin;
- formaldehyde;
- polysorbate 80; or
- CTAB (cetrimonium bromide).

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; or
- skin rash, itching or hives.

**Do not have Agrippal vaccine if you or your child have/has a temperature higher than 38.5°C or sudden illness (acute infection).**
Agrippal vaccine is not indicated for use in children under 6 months.

**Do not have Agrippal vaccine after the expiry date printed on the pack.**
The expiry date is stated on the carton after EXP. The expiry date refers to the last day of that month.

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

**If you are not sure whether you or your child should have Agrippal vaccine, talk to your doctor or pharmacist.**

### *Before you or your child are given Agrippal vaccine*

**Tell your doctor if in the past you or your child have/has reacted to vaccination with any of the following:**

- severe allergic reaction;
- difficulty breathing;
- swelling of the throat;
- fainting or collapse;
- fits or convulsions;
- high temperature (greater than 38.5°C); or
- severe skin reaction at the injection site, including severe bruising.

**Tell your doctor if you or your child have an infection or high temperature.**
Your doctor may decide to delay vaccination until your illness has passed. A minor illness such as a cold is not usually a reason to delay vaccination.

**Tell your doctor if in the past you or your child have had any medical conditions, especially the following:**

- low immunity due to ill-health, for example some blood disorders, malaria, kidney disease requiring dialysis, HIV/AIDS or cancer
- low immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines, used to treat cancer (including radiation therapy)
- allergies or allergic reactions, including: runny, blocked or itchy nose; itchy rash or hives; swelling of the face, lips, mouth or tongue
- Guillain-Barre Syndrome (GBS), an illness which affects the nervous system and causes paralysis
- bleeding problems.

**Tell your doctor if you or your child for any reason, has a blood test within a few days following a flu vaccination.**
This is because false positive blood test results have been observed in a few patients who had recently been vaccinated.

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

- any other medicines
- any other substances, such as foods, preservatives or dyes.

**Tell your doctor if you are pregnant, or are planning to become pregnant.**
Your doctor will discuss the potential risks and benefits of having Agrippal vaccine during pregnancy, and advise you on the timing of Agrippal vaccination with regards to pregnancy.

**Tell your doctor if you are breast-feeding.**
Your doctor will discuss the possible risks and benefits of having Agrippal vaccine while you are breast-feeding.

### *Taking other medicines*

**Tell your doctor or pharmacist if you or your child are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and influenza vaccines may interfere with each other. These include:

- medicines which lower the body's immune response, such as corticosteroids, cyclosporin;
- some treatments for cancer (including radiation therapy);
- warfarin, used to prevent blood clots.

These medicines may be affected by influenza vaccines. Your doctor will consider whether adjustment of your medication is necessary or whether additional tests are required after vaccination.

### *Having other vaccines*

**Tell your doctor if you have had any vaccines in the last 4 weeks.**

Your doctor will tell you if Agrippal vaccine can be given at the same visit as another vaccine.

Your doctor and pharmacist may have more information on medicines and vaccines to be careful with or avoid when you are given Agrippal vaccine.

## How Agrippal vaccine is given

Agrippal vaccine is given by injection into the muscle by a trained health professional. In adults it is usually injected into the upper arm. In babies, Agrippal vaccine is usually given in the upper thigh.

**Agrippal vaccine should not be injected directly into a blood vessel.**

Agrippal vaccine should be given at facilities able to manage any allergic reaction. Allergy to Agrippal vaccine is rare but allergy to any vaccine may occur.

### *How much is given*

Agrippal vaccine injection is given once every year, as follows:

- Adults and Children from 36 months: one injection of 0.5 mL.
- Children 6 to 35 months: one injection of 0.25 mL.

Some people may require a second (booster) injection of Agrippal vaccine 4 weeks after the first injection. Please ask your doctor if this includes you or your child.

Overdose is unlikely to have any untoward effect.

**If you have any concerns, ask your doctor or pharmacist.**

### *When it is given*

Agrippal vaccine is usually given before the start of the influenza season.

Vaccination should be repeated every year as new types of influenza virus can appear each year.

### *If you miss a dose*

Your doctor may advise that you or your child should have a second injection of Agrippal vaccine 4 weeks after the first dose. If you miss the follow-up dose, talk to your doctor and arrange another visit as soon as possible.

## After having Agrippal vaccine

### *Things you or your child must do*

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

**Keep any follow-up appointments with your doctor or clinic.**
It is important that the follow-up dose of Agrippal vaccine is taken at the appropriate time. This ensures the vaccine has the best chance of providing protection against the flu.

**If you develop any medical problems after being given Agrippal vaccine, tell your doctor.**

## Side effects

**Tell your doctor or pharmacist as soon as possible if you or your child feel unwell after having Agrippal vaccine.**
Agrippal vaccine may have unwanted side effects in some 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 for 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:**

- redness, swelling, hardness, soreness, bruising around the area where the vaccine is injected;
- fever, shivering headache, sweating, malaise (generally unwell), fatigue; or
- muscle pain or joint pain.

These are the more common side effects of Agrippal vaccine. These reactions usually disappear within 1-2 days without treatment.

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

- swelling of limbs, face, lips, eyes, inside of nose, mouth or throat;
- shortness of breath, breathing or swallowing difficulties;
- skin reactions that may spread throughout the body including hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions; or
- unusual tiredness or weakness that is sudden and severe.

These may be very serious side effects. You may need urgent medical attention or hospitalisation.

As with all vaccines given by injection there is a very small risk of such reactions. Allergy to Agrippal is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

**Other events reported after influenza vaccination include:**

- skin reactions that may spread throughout the body including itchiness of the skin (pruritus, urticaria), rash;
- skin infection where the vaccine is injected;
- extensive swelling of the limb;
- blood vessel inflammation which may result in skin rashes (vasculitis) and in very rare cases in 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-Barre Syndrome);
- fainting or collapse;

- 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).

**Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell and if any of these events get serious.**

**Do not be alarmed by this list of possible side effects.**
You or your child may not experience any of them.

## Storage

Agrippal vaccine is usually stored in the doctor's surgery or clinic, or at the pharmacy.

If you need to store Agrippal vaccine:

- Keep it where children cannot reach it.
- Keep Agrippal vaccine 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 Agrippal vaccine. Protect it from light.

Note: Freezing destroys the vaccine.

Agrippal vaccine should not be used after the expiry date on the label. The expiry date is stated on the carton after EXP. The expiry date refers to the last day of that month.

## Product description

### *What it looks like*

Agrippal vaccine is a clear colourless liquid in a pre-filled disposable syringe for single usage only. Your trained health professional will give you the injection.

Each pre-filled syringe (type I glass) contains a 0.5 mL dose of vaccine. Packs of 1 or 10 pre-filled syringes.

### *Ingredients*

**Active ingredients:**
Influenza virus surface antigens (haemagglutinin and neuraminidase) of the following strains:

- A (H1N1) strain 15 micrograms HA*; and
- A (H3N2) strain 15 micrograms HA*; and
- B strain 15 micrograms HA*

for the Southern Hemisphere flu season 2015.

* haemagglutinin

**Other ingredients:**

- Sodium chloride 4.0 mg;
- Potassium chloride 0.1 mg;
- Potassium dihydrogen phosphate 0.1 mg;
- Sodium phosphate, dibasic 0.66 mg;
- Magnesium chloride 0.05 mg;
- Calcium chloride 0.06 mg; and
- Water for Injections up to 0.5 mL.

Agrippal vaccine may also contain residues of the following substances: egg proteins and chicken proteins (the vaccine does not contain more than 0.2 mcg of ovalbumin per 0.5 mL dose and 0.1 mcg of ovalbumin per 0.25 mL dose), kanamycin sulfate, neomycin sulfate, formaldehyde, barium sulfate, sodium citrate, sucrose, cetrimonium bromide (CTAB) and polysorbate 80.

One dose of Agrippal (0.5 mL) contains less than 1 mmol (39 mg) potassium and less than 1 mmol (23 mg) sodium. This means that Agrippal is essentially free from potassium and sodium.

Agrippal vaccine does not contain thiomersal, lactose or gluten.

Agrippal is not made with any human blood or blood products, or any other substances of human origin.

**Ask your doctor or pharmacist if you are unsure about anything or want more information about Agrippal vaccine.**

## Supplier

Agrippal vaccine is supplied in Australia by:
**Novartis Vaccines and Diagnostics Pty Ltd**
54 Waterloo Road
North Ryde NSW 2113

**Registration number:**
AUST R 144670

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**For medical enquiries please contact 1800 671 203 (phone) or medinfo.phauno@novartis.com (email).**

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