PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

AGRIPPAL 2016/2017, Suspension for injection in pre-filled syringe

Influenza vaccine, Surface Antigen, Inactivated

Read all of this leaflet carefully before you or your child receive the vaccine because it contains important information for you.

- 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. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What AGRIPPAL is and what it is used for
2. What you need to know before you or your child use AGRIPPAL
3. How to use AGRIPPAL
4. Possible side effects
5. How to store AGRIPPAL
6. Contents of the pack and other information

1. What Agrippal is and what it is used for

Agrippal is a vaccine. This vaccine helps to protect you or your child against influenza (flu), particularly in subjects who run a high risk of associated complications. The use of Agrippal should be based on official recommendations.

When a person is given the vaccine Agrippal, 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 strains that can change every year. Therefore, this is why you or your child might need to be vaccinated every year. The greatest risk of catching flu is during the cold months between October and March. If you or your child was not vaccinated in the autumn, it is still sensible to be vaccinated up until the 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.

Agrippal will protect you or your child against the three strains of virus contained in the vaccine from about 2 to 3 weeks after 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.

2. What you need to know before you or your child use Agrippal

To make sure that Agrippal is suitable for you or your child, it is important to tell your doctor or pharmacist if any of the points below apply to you or your child. If there is anything you do not understand, ask your doctor or pharmacist to explain.

Do not use Agrippal
- If you or your child is allergic (hypersensitive) to:
  - the active substances, or
  - any of the other ingredients of Agrippal, see section 6 *"Contents of the pack and other information"*, or
  - any component that may be present in very small amounts such as eggs (ovalbumin or chicken proteins), kanamycin and neomycin sulphate, formaldehyde, cetyltrimethylammonium bromide (CTAB), polysorbate 80 and barium sulphate.

- If you or your child has had an anaphylactoid reaction to previous influenza vaccination.

- If you or your child has an illness with a high temperature or acute infection, the vaccination shall be postponed until after you or your child has recovered.

Warnings and precautions
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).

Fainting, feeling faint or other stress related reactions can occur as a response to any needle injection. Tell your doctor or nurse if you have experienced this kind of reaction previously

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

If, for any reason, you or your child has a blood test within a few days following a 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, Agrippal may not fully protect all persons who are vaccinated.

Latex-sensitive individuals:
Although no natural rubber latex is detected in the syringe tip cap, the safe use of Agrippal in latex-sensitive individuals has not been established.

Other medicines and Agrippal
- Tell your doctor or pharmacist if you or your child is taking, has recently taken or might take other vaccines or any other medicines, including medicines obtained without a prescription.

- Agrippal can be given at the same time as other vaccines by using separate limbs. It should be noted that the side effects may be stronger.

- A higher frequency of some solicited systemic reactions has been reported in subjects vaccinated with trivalent inactivated influenza vaccine and pneumococcal vaccine compared with trivalent inactivated influenza vaccine alone.

- The immunological response may decrease in case of immunosuppressant treatment, such as corticosteroids, cytotoxic drugs or radiotherapy.

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 flu vaccines do not indicate that the vaccine would have harmful effects on the pregnancy or the baby.

Agrippal may be used during breast-feeding.

Your doctor/pharmacist will be able to decide if you should receive Agrippal.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Agrippal has no or negligible influence on the ability to drive or use machines.

Important information about some of the ingredients of Agrippal
Agrippal does not contain more than 0.2 µg of ovalbumin per 0.5 ml dose and 0.1 µg of ovalbumin per 0.25 ml dose.

1 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.

3. How to use Agrippal

Dose

Adults receive one 0.5 ml dose.

Use in children
Children from 36 months and older receive one 0.5 ml dose.
Children from 6 months to 35 months may receive either one 0.25 ml dose or one 0.5 ml dose in accordance with existing national recommendations.
If your child has not been previously vaccinated against flu, a second dose should be given after at least 4 weeks.

Route(s) and/or method of administration

Your doctor will administer the recommended dose of the vaccine as an injection into the muscle or deep under the skin.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Agrippal 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 (ecchymosis), hardness (induration) around the area where the vaccine is injected.

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

Next to the above common side effects, 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 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, fainting, feeling faint, 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)
- 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 (thrombocytopenia); swelling of the glands in the neck, armpit or groin (lymphadenopathy)
- swelling, pain and redness at the injection site extending to more than 10 cm and lasting more than one week (Injection site cellulitis-like reaction)
- extensive swelling of injected limb lasting more than one week.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Agrippal

Keep out of the sight and reach of children.

Do not use Agrippal after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Agrippal contains
The active substances are:

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

A/California/7/2009 (H1N1) pdm09 – like strain (A/California/7/2009, NYMC X-181)

15 micrograms HA**

A/Hong Kong/4801/2014 (H3N2) – like strain (A/Hong Kong/4801/2014, NYMC X-263B)

15 micrograms HA**

B/Brisbane/60/2008 – like strain (B/Brisbane/60/2008, wild type)

15 micrograms HA**

Per 0.5 ml dose

*propagated in fertilized hens' eggs from healthy chicken flocks
** haemagglutinin

This vaccine complies with the WHO (World Health Organisation) recommendations (Northern hemisphere) and EU decision for the 2016/2017 season.

The other ingredients are:
Sodium chloride; potassium chloride; potassium dihydrogen phosphate; disodium phosphate dihydrate; magnesium chloride hexahydrate; calcium chloride dihydrate and water for injections.

What Agrippal looks like and contents of the pack
Agrippal is a suspension for injection in pre-filled syringe of 0.5 ml, with or without needles.
Pack size of 1 or 10.
Not all the pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Seqirus S.r.l.
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Seqirus Vaccines Ltd.
Gaskill Road Speke Liverpool L24 9GR, UK

This medicinal product is authorised in the Member States of the EEA under the following names:
Belgium, Cyprus, Croatia, Denmark, Finland, France, Greece, Hungary, Ireland, Luxembourg, Netherlands, Sweden, UK: Agrippal
Italy: Agrippal S1
Portugal and Spain: Chiroflu
Germany: Begripal
Austria: Sandovac

This leaflet was last revised in 08/2016.

The following information is intended for healthcare professional only:

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

The vaccine should be allowed to reach room temperature before use.
Discard if the vaccine has been frozen.
Shake before use. After shaking, the normal appearance of Agrippal is a clear liquid. Visually inspect Agrippal for the presence of particulate matter or discoloration prior to administration. If either of these conditions exists, do not use the contents.
When using a pre-filled syringe supplied without a needle, remove the tip cap from the syringe and then attach a suitable needle for administration.

When administering a half dose (0.25 ml), discard half the contained volume by holding the syringe in an upright position and pushing the plunger until the front edge of the stopper reaches the mark indicated on the syringe barrel. Inject the entire remaining 0.25 ml contents of the syringe.
It must not be mixed with other medicinal products.
Agrippal should under no circumstances be administered intravascularly.