

Novartis Vaccines

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Summary of Product Characteristics last updated on the eMC: 01/11/2013

Agrippal Influenza vaccine (surface antigen, inactivated)

1. Name of the medicinal product

AGRIPPAL, Suspension for injection in pre-filled syringe

Influenza vaccine (surface antigen, inactivated)

(2013/2014 SEASON)

2. Qualitative and quantitative composition

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

A/California/7/2009 (H1N1)pdm09 – derived strain used (NYMC X-181) 15 micrograms HA**

A/Victoria/361/2011 (H3N2)– like strain used (NYMC X-223) derived from A/Texas/50/2012 15 micrograms HA**

B/Massachusetts/2/2012-like strain used B/Massachusetts/2/2012 wild type 15 micrograms HA**

Per 0.5 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks

** haemagglutinin

This vaccine complies with the WHO recommendations (northern hemisphere) and EU decision for the 2013/2014 season.

Excipients:

For a full list of excipients see section 6.1

Agrippal may contain traces of eggs such as ovalbumin or chicken proteins, kanamycin and neomycin sulphate, formaldehyde, cetyltrimethylammonium bromide (CTAB), polysorbate 80 and barium sulphate which are used during the manufacturing process (see section 4.3).

3. Pharmaceutical form

Suspension for injection in pre-filled syringe.

The vaccine appears as a clear liquid.

4. Clinical particulars

4.1 Therapeutic indications

Prophylaxis of influenza, especially in those who run an increased risk of associated complications.

Agrippal is indicated in adults and children from 6 months of age.

The use of AGRIPPAL should be based on official recommendations.

4.2 Posology and method of administration

Posology

Adults: 0.5 ml.

Paediatric population

Children from 36 months onwards: 0.5 ml

Children from 6 months to 35 months: Clinical data are limited. Dosages of 0.25 ml or 0.5 ml may be given. The dose given should be in accordance with the existing national recommendation.

For children who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

Children less than 6 months: the safety and efficacy of Agrippal in children less than 6 months have not been established.

No data are available

Method of administration

Immunisation should be carried out by intramuscular or deep subcutaneous injection.

Precautions to be taken before handling or administering the medicinal product

For instructions for preparation of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), kanamycin and neomycin sulphate, formaldehyde, cetyltrimethylammonium bromide (CTAB), polysorbate 80 and barium sulphate.

Immunisation shall be postponed in patients with febrile illness or acute infection.

4.4 Special warnings and precautions for use

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.

Agrippal should under no circumstances be administered intravascularly.

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

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.

Interference with serological testing

See section 4.5.

4.5 Interaction with other medicinal products and other forms of interaction

Agrippal may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.

The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA results. The transient false positive reactions could be due to the IgM response by the vaccine.

4.6 Fertility, pregnancy and lactation

Pregnancy

Inactivated influenza 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 foetal and maternal outcomes attributable to the vaccine.

Breastfeeding

Agrippal may be used during breastfeeding.

Fertility

No fertility data are available.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

ADVERSE REACTIONS OBSERVED FROM CLINICAL TRIALS

The safety of trivalent inactivated influenza vaccines is assessed in open label, uncontrolled clinical trials performed as annual update requirement, including at least 50 adults aged 18 – 60 years of age and at least 50 elderly aged 61 years or older. Safety evaluation is performed during the first 3 days following vaccination.

The following undesirable effects have been observed during clinical trials with the following frequencies:

Very common ($\geq 1/10$); common ($\geq 1/100$, $< 1/10$); uncommon ($\geq 1/1,000$, $< 1/100$).

Tabulated list of adverse reactions.

Organ class	Very common $\geq 1/10$	Common $\geq 1/100$, $< 1/10$	Uncommon $\geq 1/1,000$, $< 1/100$
Nervous system disorders		Headache*	
Skin and subcutaneous tissue disorders		Sweating*	
Musculoskeletal and connective tissue disorders		Myalgia, arthralgia*	
General disorders and administration site conditions		Fever, malaise, shivering, fatigue. Local reactions: redness, swelling, pain, ecchymosis, induration*	

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

ADVERSE REACTIONS REPORTED FROM POST-MARKETING SURVEILLANCE

Adverse reactions reported from post marketing surveillance are, next to the reactions which have also been observed during the clinical trials, the following:

Blood and lymphatic system disorders:

Thrombocytopenia (some very rare cases were severe with platelet counts less than 5,000 per mm³), lymphadenopathy

General disorders and administration site conditions:

Injection-site cellulitis-like reaction (some cases of swelling, pain, and redness extending more than 10 cm and lasting more than 1 week).

Immune system disorders:

Allergic reactions, in rare cases leading to shock, angioedema

Nervous system disorders:

Neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain-Barré syndrome

Vascular disorders:

Vasculitis associated in very rare cases with transient renal involvement

Skin and subcutaneous tissue disorders:

Generalised skin reactions including pruritus, urticaria or non-specific rash

4.9 Overdose

Overdosage is unlikely to have any untoward effect.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC code: J07BB02.

Seroprotection is generally obtained within 2 to 3 weeks. The duration of postvaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6-12 months.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical particulars

6.1 List of excipients

Sodium chloride

Potassium chloride

Potassium dihydrogen phosphate

Disodium phosphate dihydrate

Magnesium chloride hexahydrate

Calcium chloride dihydrate

Water for Injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

1 year.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

0.5 ml of suspension in pre-filled syringe (type I glass) with needle (23 G, 1" or 25 G, 1" or 25 G, 5/8"), equipped with a rubber plunger stopper – pack size of 1 or 10.

0.5 ml of suspension in pre-filled syringe (type I glass) without needle, equipped with a rubber plunger stopper – pack size of 1 or 10.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

The vaccine should be allowed to reach room temperature before use.

Shake before use. After shaking, the normal appearance of Agrippal is a clear liquid.

Inspect Agrippal visually 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.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Novartis Vaccines and Diagnostics S.r.l., Via Fiorentina 1, SIENA, Italy

8. Marketing authorisation number(s)

PL 13767/0004

9. Date of first authorisation/renewal of the authorisation

22 December 1998 / 22 January 2009

10. Date of revision of the text

09/2013

UK/AGR/13-0001 October 2013