

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Agrippal Suspension for injection in pre-filled syringe, Influenza Vaccine Surface Antigen, Inactivated(2017/2018 season)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

A/Guandong-Maonan/SWL1536/2019 (H1N1)pdm09-like strain (A/Victoria/2454/2019 IVR-207)
15 micrograms HA**

A/Hong Kong/2671/2019 (H3N2)-like strain (A/Hong Kong/2671/2019 IVR-208)
15 micrograms HA**

B/Washington/02/2019-like strain (B/Victoria/705/2018 BVR-11)
15 micrograms HA**

*propagated in fertilized hens' eggs from healthy chicken flocks

**haemagglutinin

For one dose of 0.5 ml

This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and EU recommendation for the 2020/2021 season.

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

For the full list of excipients see section 6.1.

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

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 or residues (e.g., egg or chicken proteins, such as ovalbumin).

Known hypersensitivity to any of the following substances, possibly contained as residues:
kanamycin and neomycin sulphate, formaldehyde, cetyltrimethylammonium bromide (CTAB), polysorbate 80 and hydrocortisone.

Previous anaphylactoid reaction to any influenza vaccination.

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

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

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.

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

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

Latex-sensitive individuals:

Presentation supplied with attached needle: The needle shield of the pre-filled syringe supplied with an attached needle contains dry natural rubber latex that may cause hypersensitivity reactions in latex-sensitive individuals.

Presentation supplied without needle: None of the components in the presentation supplied without needle contain dry natural rubber latex. (see section 6.5)

4.5 Interaction with other medicinal products and other forms of interactions

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.

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 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 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 ($\geq 1/1,000$, $< 1/100$); rare ($\geq 1/10,000$, $< 1/1,000$); very rare ($< 1/10,000$), including isolated reports.

Nervous system disorders

Common ($\geq 1/100$, $< 1/10$): Headache*

Skin and subcutaneous tissue disorders

Common ($\geq 1/100$, $< 1/10$): Sweating*

Musculoskeletal and connective tissue disorders

Common ($\geq 1/100$, $< 1/10$): Myalgia, arthralgia*

General disorders and administration site conditions

Common ($\geq 1/100$, $< 1/10$): 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), extensive swelling of injected limb lasting more than one 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 Guillain-Barré syndrome, syncope, presyncope.

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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRC Pharmacovigilance, Website: www.hpra.ie.

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

Non-clinical data reveal no special hazard for humans based on animal studies that are appropriate for the safety assessment of vaccines.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride, potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, magnesium chloride hexahydrate, calcium chloride dihydrate and 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. Syringes without needle may be fitted with a Luer Lock system.

Not all pack sizes may be marketed.

The needle shield of the pre-filled syringe supplied with an attached needle contains dry natural rubber latex (see section 4.4). None of the components in the presentation supplied without needle contain dry natural rubber latex.

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.

Visually inspect Agrippal for the presence of particulate matter or discoloration prior to administration. If either of these conditions exists, do not use the content.

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. For Luer Lock syringes, remove the tip cap by unscrewing it in a counter-clockwise direction. Once the tip cap is removed, attach a needle to the syringe by screwing it on in a clockwise direction until it locks. Once the needle is locked in place, remove the needle protector and administer the vaccine.

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

Seqirus S.r.l.
Via del Pozzo 3/A
S. Martino
53035 Monteriggioni
Siena
Italy

8 MARKETING AUTHORISATION NUMBER

PA2032/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 19th February 1999

Date of last renewal: 18th February 2009

10 DATE OF REVISION OF THE TEXT

August 2020