INFLUENZA VACCINE, SURFACE ANTIGEN, INACTIVATED

2010/2011 Season

AGRIPPAL™ S1

J07BB02

Suspension For Injection In Pre-filled Syringe

Composition.
AGRIPPAL S1 is an influenza vaccine. One dose (0.5 ml) contains:
Active ingredients: Influenza virus surface antigens (haemagglutinin and neuraminidase), propagated in fertilized hen's eggs from healthy chicken flocks, of the following strains:

A/California/07/2009 (H1N1) -like strain (A/California/07/2009, NYMC X-181)	15 micrograms HA*
A/Perth/16/2009 (H3N2) -like strain (A/Victoria/210/2009, NYMC X-187)	15 micrograms HA*
B/Brisbane/60/2008 – like strain (B/Brisbane/60/2008)	15 micrograms HA*

* viral haemagglutinin

Excipients: sodium chloride; potassium chloride; potassium dihydrogen phosphate; disodium phosphate dihydrate; magnesium chloride; calcium chloride and water for injection.
This vaccine complies with the WHO recommendations (northern hemisphere) and EU decision for the 2010/2011 season.

Pharmaceutical form and contents.
Suspension for injection in pre-filled syringe.
1x single dose (0.5 ml) pre-filled syringe with needle 25G, 5/8".
The vaccine appears as a clear liquid.

Pharmacotherapeutic category.
Influenza vaccine.

Indications.
Influenza prophylaxis, especially in those subjects who run an increased risk of influenza-associated complications.
The use of AGRIPPAL S1 should be based on official recommendations.

Contraindications.
Hypersensitivity to the active substances, to any of the excipients and to residues (see below).
The vaccine may contain residues of the following substances, e.g. eggs, chicken proteins, kanamycin and neomycin sulphate, formaldehyde, cetyltrimethylammonium bromide (CTAB) and polysorbate 80.
Immunisation shall be postponed in patients with febrile illness or acute infection.

Precautions for use.
As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.
AGRIPPAL S1 should under no circumstances be administered intravascularly.

Important information about some of the ingredients of AGRIPPAL S1.
AGRIPPAL S1 does not contain more than 0.2 µg of ovalbumin per 0.5 ml dose and 0.1µg of ovalbumin per 0.25 ml dose.

Interactions.
AGRIPPAL S1 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 results. The transient false positive reactions could be due to the IgM response by the vaccine.

Special warnings.
Antibody response in patients with endogenous (due to illness) or iatrogenic (due to medicine) immunosuppression may be insufficient.

Pregnancy and lactation.
Limited data from vaccinations in pregnant women do not indicate that adverse foetal and maternal outcomes were attributable to the vaccine. The use of this vaccine may be considered from the second trimester of pregnancy. For pregnant women with medical conditions that increase their risk of complications from influenza, administration of the vaccine is recommended, irrespective of their stage of pregnancy.
AGRIPPAL S1 may be used during lactation.

Effects on ability to drive and use machines.
AGRIPPAL S1 is unlikely to produce an effect on the ability to drive and use machines.

Dosage, method and time of administration.
- Adults and children over 36 months of age: 0.5 ml
- Children from 6 to 35 months of age: clinical data are limited. Doses of 0.25 ml or 0.5 ml have been used.

For children who have not been previously vaccinated, a second dose should be given after an interval of at least 4-weeks.
If half a dose (0.25 ml) is to be administered, discard half the contained volume (up to the mark indicated on the syringe barrel), before injection.
The vaccine should be administered by intramuscular or deep subcutaneous injection. AGRIPPAL S1 should be allowed to reach room temperature before use. Shake before use.

Overdose.
Overdosage is unlikely to have any untoward effect.

Undesirable effects.
Like all medicines AGRIPPAL S1 can have side effects.

Adverse reactions observed from clinical trials.
The following undesirable effects have been observed during clinical trials with the following frequencies:
Very common; common; uncommon; rare; very rare, including isolated reports.

Nervous system disorders
Common:
Headache*.

Skin and subcutaneous tissue disorders
Common:
Sweating*.

Musculoskeletal and connective tissue disorders
Common:
Myalgia, arthralgia*.

General disorders and administration site conditions
Common:
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:
Transient thrombocytopenia, transient lymphadenopathy.

Immune system disorders:
Allergic reactions, in rare cases leading to shock, angio-edema.

Nervous system disorders:
Neuralgia, paraesthesiae, 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.
Allergic reactions, in rare cases leading to shock [the symptoms of serious allergic reaction (anaphylactic reaction) are: serious and sudden hypotension, acceleration or slowing down of heartbeat, unusual fatigue or weakness, anxiety, nervousness, loss of consciousness, breathing and deglutition problems, itching (especially under the feet or on the palms of hands), urticaria with or without angioedema (swollen and itchy skin areas more frequently around extremities, external genitalis and face, especially around the eyes and lips), rash (especially around the ears), nausea, vomiting, cramp-like stomach-ache, diarrhoea], have been reported.

These undesirable effects are generally transient. When they appear it is advisable to consult a physician.
It is important to inform the physician of the appearance of any undesirable effects not described on this leaflet.

Shelf-life and storage.
Do not use the product after the expiry date indicated on the box. Information regarding the medicinal product should always be kept at hand, therefore keep both the box and the package leaflet. AGRIPPAL S1 must be stored in a refrigerator (2°C - 8°C). Do not freeze. Keep the syringe in the outer carton in order to protect from light. Keep medicines out of the reach of children.

Manufacturer: Novartis Vaccines and Diagnostics S.r.l., Via Fiorentina 1, Siena- Italia.

Marketed by: Chiron Panacea Vaccines Pvt. Ltd.
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CHIRON Panacea VACCINES

NOVARTIS VACCINES

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