

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE MEDICINAL PRODUCT**

AGRIPPAL

Suspension for injection in pre-filled syringe

Influenza vaccine (surface antigen, inactivated)

(2005/2006 season)

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

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

A/New Caledonia/20/99 (H1N1) - like strain (A/New Caledonia/20/99 IVR-116)  
15 micrograms \*\*

A/California/7/2004 (H3N2) - like strain (A/New York/55/2004 NYMC X-157)  
15 micrograms\*\*

B/Shanghai/361/2002 - like strain (B/Jiangsu/10/2003)  
15 micrograms \*\*

For one dose of 0.5 ml.

\* propagated in eggs, inactivated by formaldehyde

\*\*haemagglutinin

This vaccine complies with the WHO recommendations (northern hemisphere) and EU decision for the 2005/2006 season.

For excipients see 6.1

### **3. PHARMACEUTICAL FORM**

Suspension for injection in pre-filled syringe.

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

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

## **4.2 Posology and method of administration**

Adults and children from 36 months: 0.5 ml

Children from 6 months to 35 months: Clinical data are limited. Dosages of 0.25 ml or 0.5 ml have been used.

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

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

## **4.3 Contra-indications**

Hypersensitivity to the active substances, to any of the excipients and to 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.

## **4.4 Special warnings and special 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.

The vaccine (AGRIPPAL) should under no circumstances be administered intravascularly.

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

## **4.5 Interactions with other medicaments and other forms of interaction**

The vaccine (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 results. The transient false positive reactions could be due to the IgM response to the vaccine.

#### **4.6 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.

The vaccine (AGRIPPAL) may be used during lactation.

#### **4.7 Effects on ability to drive and use machines**

The vaccine is unlikely to produce an effect on the ability to drive and use machines.

#### **4.8 Undesirable effects**

Adverse reactions 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 60 years or older. Safety evaluation is performed during the first 3 days following vaccination.

Undesirable effects reported are listed according to the following frequency.

Adverse events from clinical trials:

Common (>1/100, <1/10):

Local reactions: redness, swelling, pain, ecchymosis, induration.

Systemic reactions: fever, malaise, shivering, fatigue, headache, sweating, myalgia, arthralgia.

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

From Post-marketing surveillance additionally, the following adverse events have been reported:

Uncommon (>1/1,000, <1/100):

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

Rare (>1/10,000, <1/1,000):

Neuralgia, paraesthesia, convulsions, transient thrombocytopenia.

Allergic reactions, in rare cases leading to shock, have been reported.

Very rare (<1/10,000):

Vasculitis with transient renal involvement. Neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome.

#### **4.9 Overdose**

Overdosage is unlikely to have any untoward effect.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic Properties**

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.

ATC code J07BB02.

#### **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, Calcium chloride 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**

This product should be stored at +2°C to +8°C (in a refrigerator).

Do not freeze. Protect from light.

#### **6.5 Nature and contents of the container**

0.5 ml of suspension for injection in a pre-filled syringe (type I glass) equipped with a rubber plunger stopper, presented with or without a needle.

Pack of 1, with needle (23 G, 1'' or 25 G, 1'' or 25 G, 5/8'') or without needle.

Pack of 10x, with needle (23 G, 1'' or 25 G, 1'' or 25 G, 5/8'') or without needle.

#### **6.6 Instructions for use / handling**

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

Shake before use.

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.

### **7. MARKETING AUTHORISATION HOLDER**

Chiron S.r.l., Via Fiorentina 1, SIENA, Italy

### **8. MARKETING AUTHORISATION NUMBER**

PA 919/1/1

### **9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION**

19 February 1999

### **10. DATE OF (PARTIAL) REVISION OF TEXT**

June 2005