Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fluvirin, Suspension for injection in pre-filled syringe. [Influenza Vaccine (Surface antigen, Inactivated) Ph. Eur.]

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus surface antigens (haemagglutinin and neuraminidase) propagated in embryonated chicken eggs, inactivated by betapropiolactone, split by nonoxynol 9 and purified, of strains:

A/New Caledonia/20/99 (H1N1) - like strain (A/New Caledonia/20/99 (IVR-116)) Ph. Eur.	15	micrograms** Haemagglutinin
A/Fujian/411/2002(H3N2) – like strain (A/Wyoming/3/2003 X-147)	15	micrograms** Haemagglutinin
B/Shanghai/361/2002 - like strain (B/Jiangsu/10/2003)	15	micrograms** Haemagglutinin

per 0.5 ml dose.

This vaccine complies with the WHO recommendation (northern hemisphere) and EU decision for the year 2004/2005.

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 4 years: 0.5 ml.

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 Contraindications

Hypersensitivity to the active substances, to any of the excipients and to eggs, chicken proteins, betapropiolactone, nonoxynol 9, neomycin, polymyxin, formaldehyde, or thiomersal.

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 a rare anaphylactic event following the administration of the vaccine.

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

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

Thiomersal (an organomercuric compound) has been used in the manufacturing process of this medicinal product and residues of it are present in the final product. Therefore sensitisation reactions may occur. The maximum thiomersal content in FLUVIRIN® is 0.005mg (0.001% w/v).

4.5 Interaction with other medicinal products and other forms of interaction

The vaccine (FLUVIRIN®) 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.

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 (FLUVIRIN®) 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 accordingly 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):
Gereralised skin reactions including pruritus, urticaria or non-specifioc 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.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Buffer solution:
Potassium dihydrogen phosphate
Disodium hydrogen phosphate
Sodium chloride
Water for injection

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 at +2°C to +8°C (in a refrigerator). Do not freeze. Keep container in the original carton.

6.5 Nature and contents of container

0.5 ml in pre-filled syringe (glass, type 1) with stopper (rubber), fitted with a stainless steel needle, pack of 1, 10, 20 and 50 syringes.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

7 MARKETING AUTHORISATION HOLDER

Chiron Vaccines Limited
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Speke
Liverpool
L24 9GR
UK

8 MARKETING AUTHORISATION NUMBER

PA 1001/5/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 August 1998

Date of last renewal: 30 December 2002

10 DATE OF REVISION OF THE TEXT

November 2005