SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT

POULVAC Flufend i-AI H5N9 H7N1

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients
Inactivated Avian Influenza Virus, H5N9
Strain A/CK/Italy/22A/H5N9/1998

Inactivated Avian Influenza Virus, H7N1
Strain A/CK/Italy/1067/H7N1/1999

Inducing an HI titre of ≥1:64 for each subtype as tested according to the potency test

Constituents of the adiuvant
White oil
Sorbitan sesquioleate
Polysorbate 80

Excipients
Thimerosal

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens, ducks and turkeys

4.2 Indications for use, specifying the target species

For active immunisation of chickens, ducks and turkeys as an aid in the control of infections with avian influenza serotypes H5 and H7. Efficacy has been evaluated on the basis of preliminary results. Protection against clinical signs and mortality and reduced viral excretion were shown by three weeks after completion of the primary course. Significant antibody titres have been shown to persist in chickens for at least 22 weeks.

4.3 Contraindications

Do not use in unhealthy chickens, ducks or turkeys.

4.4 Special warnings for each target species

Avoid stress in the birds around the time of vaccination.

There is no information on efficacy of the vaccine in the presence of maternal antibody that may be present in very young progeny of birds which have been vaccinated.

The vaccine should be used as part of a co-ordinated disease control programme together with virological monitoring and strict bio-security measures.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

To the user:
This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse Reactions (frequency and seriousness)

A transient local reaction (palpable diffuse muscular swelling of about 1.5 cm diameter) may occasionally occur at the injection site, especially after repeated administration.

4.7 Use during pregnancy, lactation or lay

No information is available on the safety of this vaccine for birds in lay.

4.8 Interactions with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered shortly before or after vaccination with the product.

4.9 Amounts to be administered and administration route

Chickens from 2 weeks of age
Two doses of 0.5 ml of the vaccine should be administered by intramuscular injection with an interval of at least 14 days between vaccinations. The vaccination schedule should be complete at least 4 weeks before the start of laying.

Turkeys from 8 days of age
Three 0.5ml doses should be administered subcutaneously at intervals of approximately 21 days. The vaccination schedule should be complete at least 4 weeks before the start of laying.

Ducks from 1 day of age
One dose of 0.2 ml should be administered by the subcutaneous route in the neck followed by a second dose of 0.5 ml administered by the subcutaneous route in the neck at 3 weeks of age. The vaccination schedule should be complete at least 4 weeks before the start of laying.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No signs following administration of a double dose other than those seen with a single dose (see 4.6).

4.11 Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against avian influenza H5 and H7 serotypes.

To induce serological responses against N9 and N1 neuraminidases which could act as markers to differentiate between vaccinated and infected birds (DIVA strategy).

ATC vet code: QI01AA23, QI01BA, QI01CA

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White oil
Sorbitan sesquioleate
Polysorbate 80
Thimerosal
Phosphate Buffered Saline

6.2 Major incompatibilities

Do not mix with any other vaccine / immunological product.

6.3 Shelf life

6 months
After broaching use within one working day, providing the product is not subject to extreme temperatures or contaminated.

6.4 Special precautions for storage

Store and transport at 2 - 8°C in unopened packaging.
Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

500 ml high-density polyethylene bottles containing 1000 doses, closed with a rubber stopper and aluminium cap. The vaccine is presented in boxes of 1 or 10 bottles.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Fort Dodge Animal Health
Flanders Road
Hedge End
Southampton
SO30 4QH

8. MARKETING AUTHORISATION NUMBER

01596/4347

9. DATE OF FIRST AUTHORISATION OR DATE OF RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

March 2006

11. ANY OTHER INFORMATION REQUIRED BY THE SECRETARY OF STATE

The import, sale, supply and/or use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of Avian Influenza. Any person intending to import, sell, supply and/or use the veterinary medicinal product must be authorised by the competent authority of the member state.