SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

per 0.5 ml

Active substance
Inactivated antigen of one or two strains of Avian Influenza Type A of the following subtypes:
subtype H5N2, strain A/duck/Potsdam/1402/86
subtype H5N6, strain A/duck/Potsdam /2243/84
subtype H7N1, strain A/CK/Italy/473/99
subtype H7N7, strain A/duck/Potsdam/15/80
subtype H9N2, strain A/CK/UAE/415/99
inducing an HI titre of $\geq$6.0 $\log_2$ for each subtype included in the vaccine as tested according to the potency test.

Excipients

Adjuvant	Water in mineral oil emulsion

3. PHARMACEUTICAL FORM

Emulsion for injection

4. CLINICAL PARTICULARS

4.1 Target species

Chickens and ducks. Other avian species susceptible to avian influenza when considered at particular risk

4.2 Indications for use, specifying the target species

For active immunisation of chickens, ducks and other avian species as an aid in the control of outbreaks of avian influenza type A, subtypes H5, H7 and/or H9.
Efficacy has been evaluated on the basis of preliminary results in chickens and ducks. Protection against clinical signs, mortality, reduction of viral excretion and transmission of virus after challenge were shown by two weeks after vaccination.

Protective levels of serum antibody titres would be expected to persist for at least 12 months after administration of two doses of vaccine.

4.3 Contraindications

None

4.4 Special warnings for each target species

This vaccine has been tested for safety in chickens. It may be used in other avian species which are considered at risk of infection but its use in these species should be undertaken with care and it is advisable to test the vaccine on a small number of birds prior to mass vaccination.
The vaccine should be used as part of a co-ordinated disease control programme together with virological monitoring and strict bio-security measures.
This vaccine has been evaluated for efficacy in chickens, ducks and turkeys. It may be used in other avian species which are considered at risk of infection where it is expected to provide at least protection against clinical signs and mortality.

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

i) Special precautions for use in animals
None

ii) 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.

iii) Other precautions
None

4.6 Adverse Reactions (frequency and seriousness)

Safety has been assessed on the basis of preliminary results in chickens and ducks.

- A transient diffuse swelling may occur at the vaccination site in 50% of

the animals.

- At the injection site, there may be localised residues of vaccine for a number of weeks after vaccination and occasional signs of inflammation.

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 compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

Administer subcutaneously or intramuscularly. A dose of 0.25 to 1.0 ml may be used depending on age and target species, taking into account the following guidance.

Chickens

Vaccinate between 8-10 days of age. Laying hens and breeders should get a second vaccination 6-10 weeks after first vaccination. A dose of 0.5 ml is advised but this dose should not be given to chickens aged less than 2 weeks. A dose of 0.25 ml can be used up to an age of 6 weeks. Vaccination of chickens less than two weeks old by the intramuscular route is not recommended.

Ducks

Vaccinate from 14 days of age. Laying and breeder stock should get a second vaccination 6-10 weeks after first vaccination. A dose of 1.0 ml is advised. For ducks up to an age of 6 weeks a dose of 0.5 ml can be used.

Other avian species

Vaccinate as for chickens but a dose of up to 1.0 ml, with 0.5 ml for birds up to 6 weeks of age, may be used for some species, e.g. waterfowl.

No information is available on vaccination in the presence of maternally derived antibodies. Immunisation of progeny from vaccinated birds should therefore be delayed until such antibodies have declined.

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 virus type A, subtype H5, H7 or H9 or a combination thereof.
Selecting vaccine strains that have (a) different N component(s) to the avian influenza field virus may enable differentiation between vaccinated and infected birds using a diagnostic test to detect Neuraminidase antibodies.
ATC-vet code: QI01AA23

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid light paraffin

6.2 Incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf life

PET vials: 24 months
Glass vials: 12 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 to 8°C. Do not freeze.

6.5 Nature and composition of immediate packaging

Carton with one type II glass or PET bottle containing 250 ml or 500 ml closed with a nitryl rubber stopper and sealed with a coded aluminium cap.
Not all pack sizes may be marketed.
Note: On special request (e.g. for vaccination of zoo animals) smaller containers produced from the same material may be used for this vaccine.

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 local requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4625

9. DATE OF FIRST AUTHORISATION

21 December 2005

10. DATE OF REVISION OF THE TEXT

November 2020

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.

Approved 17 November 2020