SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza H5N2 emulsion for injection for chickens.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 0.5 ml contains:

Active substance:
Inactivated whole avian influenza virus antigen of H5N2 subtype (strain A/duck/Potsdam/1402/86), inducing an HI titre of ≥ 6.0 $\log_2$ as tested according to the potency test.

Adjuvant:
Liquid light paraffin 234.8 mg

Excipients:
For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White to nearly white homogeneous emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

For active immunisation of chickens against avian influenza type A, subtype H5.

Onset of immunity: Efficacy has been evaluated on the basis of preliminary results in chickens. Reduction of clinical signs, mortality and excretion of virus after challenge were shown by three weeks after vaccination

Duration of immunity: Not established. Serum antibodies could be expected to persist for at least 1 year after administration of two doses of vaccine.

4.3 Contraindications

Do not administer intramuscularly in chickens less than 2 weeks old.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
This vaccine has been tested for safety in chickens. If used in other avian species that are considered at risk of infection, 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 level of efficacy for other species may differ from that observed in chickens.
The level of efficacy attained may vary depending on the degree of antigenic homology between the vaccine strain and circulating field strains.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:
This veterinary medicinal 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 leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Chickens:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]

[1] A transient diffuse swelling which persists for about 14 days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also section “Contact details” of the package leaflet.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during lay.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

4.9 Amount(s) to be administered and administration route

For subcutaneous or intramuscular use.

Allow the vaccine to reach a temperature of 15 °C – 25 °C.
Shake well before use.
Use sterile syringes and needles.
It is recommended to use a closed multiject vaccination system.

From 8 – 14 days old: administer 0.25 ml subcutaneously.
From 14 days to 6 weeks old: administer 0.25 ml or 0.5 ml subcutaneously or intramuscularly.
6 weeks and older: administer 0.5 ml subcutaneously or intramuscularly.

Future laying hens and breeders: administer a second 0.5 ml dose 4-6 weeks after the first vaccination.

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

Following the administration of a double dose, no adverse events other than those described in section 4.6 have been observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Aves*; Inactivated viral vaccines, avian influenza virus.

ATCvet code: QI01AA23

The vaccine stimulates active immunity against avian influenza virus type A, subtype H5.

If the circulating avian influenza field virus has a different N component to the N2 included in the vaccine, it may be possible to differentiate between vaccinated and infected birds by using a diagnostic test to detect Neuraminidase antibodies

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Sorbitan mono-oleate
Glycine
Water for injections

6.2 Major Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:
PET bottle: 2 years.
Glass bottle: 1 year.

Shelf life after first opening the immediate packaging: use within 8 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C to 8 °C).
Do not freeze.

6.5 Nature and composition of immediate packaging

Bottle (hydrolytical type II glass or polyethylene terephthalate) of 250 ml or 500 ml closed with a nitryl rubber stopper and sealed with a coded aluminium cap.

Pack sizes:
Cardboard box with one PET or glass bottle of 250 or 500 ml

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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 01708/5044

9. DATE OF FIRST AUTHORISATION

01 September 2006

10. DATE OF REVISION OF THE TEXT

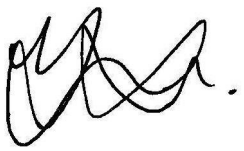
July 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.



Approved: 06 July 2023