PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (250 ml; 500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza H5N2 emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of 0.5 ml contains:
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

3. PACKAGE SIZE

250 ml
500 ml

4. TARGET SPECIES

Chickens

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular or subcutaneous use (0.25 to 0.5 ml, depending on the age).

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Keep the vial in the outer carton.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5044

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE LABEL (PET, GLASS)
250 ml/500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza H5N2 emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated whole avian influenza virus antigen of H5N2 subtype (strain A/duck/Potsdam/1402/86), inducing an HI titre of ≥6.0 $\log_2$/dose

3. TARGET SPECIES

Chickens

4. ROUTES OF ADMINISTRATION

Intramuscular or subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 8 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Keep the vial in the outer carton

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

250 ml
500 ml

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous.

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

14. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.
POM-V To be supplied only on veterinary prescription.

15. MARKETING AUTHORISATION NUMBER

Vm 01708/5044

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza H5N2 emulsion of injection for chickens.

2. 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.

White to nearly white homogeneous emulsion.

3. TARGET SPECIES

Chickens.

4. INDICATIONS FOR USE

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.

5. CONTRAINDICATIONS

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

6. SPECIAL WARNING(S)

Special warnings:
Vaccinate healthy animals only.

Special warnings for each target species:
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:
Special warning for 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.

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

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.

Overdose:
Following the administration of a double dose, no adverse events other than those described under section “Adverse events” have been observed.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. ADVERSE EVENTS

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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

Email: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For subcutaneous or intramuscular use.

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

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 8 hours.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 0178/5044

Pack sizes:
Cardboard box with 250 or 500 ml multidose glass bottle.
Cardboard box with 250 or 500 ml multidose PET bottle.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

July 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

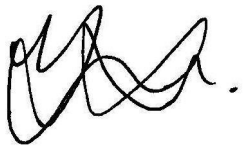
17. OTHER INFORMATION

For animal treatment only.

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.

The use of this veterinary medicinal product is only allowed under the particular conditions established by the relevant regional legislation on the control of Avian Influenza.

POM-V To be supplied only on veterinary prescription.



Approved: 06 July 2023