

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Diluent Oculo Nasal

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Sterile phosphate buffered saline. Also contains EDTA and Patent Blue V

3. PHARMACEUTICAL FORM

Sterile diluent

4. PACKAGE SIZE

31.5 ml
10 x 31.5 ml

5. TARGET SPECIES

6. INDICATION(S)

Sterile diluent for reconstitution of Nobilis live vaccines licensed for Oculo/nasal administration to poultry.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

LABEL: Read instructions supplied with the vaccine carefully before use

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

10 x 31.5 ml: Use diluent immediately on opening.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

Do not store above 25°C.

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

POM-V

For animal treatment only. To be supplied only on veterinary prescription

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd

Walton Manor

Walton

Milton Keynes

MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4502

17. MANUFACTURER’S BATCH NUMBER

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer:

Intervet International BV
Wim de Korverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Diluent Oculo Nasal

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Diluent does not contain active ingredients

Sterile phosphate buffered saline

Also contains EDTA and Patent Blue V

4. INDICATION(S)

Diluent for reconstitution of Nobilis live vaccines licensed for Oculo/nasal administration to poultry.

5. CONTRAINDICATIONS

Any contra-indications specified for the vaccine for which the diluent is used for reconstitution will apply.

6. ADVERSE REACTIONS

Any adverse effects specified for the vaccine for which Nobilis Diluent Oculo Nasal is used as the diluent will apply.

7. TARGET SPECIES

Poultry

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

The instructions supplied with the vaccine should be read carefully before using the diluent.

9. ADVICE ON CORRECT ADMINISTRATION

For freeze dried vaccines the contents of the diluent vial should be transferred aseptically into the vial of freeze-dried vaccine immediately prior to use.

10. WITHDRAWAL PERIOD(S)

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Keep the container in the outer carton

12. SPECIAL WARNING(S)

Use diluent immediately on opening

In-use shelf life is that specified for the vaccine for which Nobilis Diluent Oculo Nasal is used as the diluent.

Do not use after expiry date stated on the label

For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2021

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription

Vm 01708/4502

The product is supplied in cartons with 10 PET vials containing 31.5 or 79 ml closed with a halogenated butylrubber stopper and an aluminium crimp cap.

Not all presentations may be marketed.

Approved 12 February 2021

A handwritten signature in black ink, consisting of a stylized initial 'A' followed by the name 'Hunter.' with a period.