PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Rhino CV

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose: $10^{1.5}$ $TCID_{50}$ — - $10^{3.7}$ $TCID_{50}$ of live attenuated avian rhinotracheitis virus strain 11/94

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for oculonasal or spray application.

4. PACKAGE SIZE

1 x 1,000 ds
10 x 1,000 ds
10 x 5,000 ds

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

Vaccine against avian rhinotracheitis virus infections.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For oculonasal or spray administration.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP end of: {month/year}

11. SPECIAL STORAGE CONDITIONS

Store at +2 °C to +8 °C.
Do not freeze. Protect from light.
Keep the vials in the outer carton.
Once reconstituted use within 2 hours.

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

Dispose of waste material in accordance with local requirements.
Disposal: read package leaflet.

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

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

MA holder in the UK
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

MA holder in Ireland and distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive, Magna Business
Park, Citywest Road, Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4505

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Rhino CV

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per dose $10^{1.5}$ $TCID_{50}$ - ≤ $10^{3.7}$ $TCID_{50}$ of live att. avian rhinotracheitis virus.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 x 1,000 doses
10 x 5,000 doses

4. ROUTE(S) OF ADMINISTRATION

Oculonasal or spray administration.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch No: {number}

7. EXPIRY DATE

EXP end of: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR:
Nobilis RHINO CV

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

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

IE only
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24
Ireland

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Rhino CV

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

Per dose min. $10^{1.5}$ $TCID_{50}$* and max. 103.7 $TCID_{50}$ of live attenuated avian rhinotracheitis virus strain 11/94.
*Tissue culture infective dose 50%

4. INDICATION(S)

For broilers, future layers and breeders from one day of age.
Broilers, future layers and breeders
Active immunisation in order to reduce the frequency and the severity of clinical signs due to infection with avian rhinotracheitis virus (avian metapneumovirus). The onset of immunity is 3 weeks and the duration of immunity is 16 weeks post-vaccination.
Future layers and breeders

Priming with Nobilis Rhino CV, followed by a second vaccination with an inactivated vaccine containing the avian rhinotracheitis virus strain But1#8544 before the onset of lay results in a reduction of the clinical signs including egg drop, caused by infection with avian rhinotracheitis virus. Protective immunity is maintained for the normal laying period.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In a low percentage of flocks (less than 10 %), vaccination can lead to slight nasal discharge or coughing by some birds between 2 to 7 days after administration for 1 to 2 days.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens.

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

Oculonasal administration via eye- or nose-drop method or via coarse spray, one dose per bird from 1 day old.

9. ADVICE ON CORRECT ADMINISTRATION

Oculonasal route
Reconstitute the freeze-dried vaccine in clean, disinfectant- and antisepticfree water to which 2 % liquid skimmed milk is added and administer by means of a standardised dropper. The amount of fluid required for eye- or nose-drop administration depends on the number of doses and the droplet size, but approximately 35 ml per 1,000 doses is used. Apply one drop in a nare or eye. Check that the drop is entirely absorbed before releasing the bird.
Spray vaccination
The vaccine must be reconstituted with clean, disinfectant- and antiseptic free water to which 2 % of liquid skimmed milk is added. The appropriate number of vials must be opened under water. The volume of vaccine suspension must be sufficient to ensure a homogeneous vaccination of the
birds.
Depending on the age of the chickens to be vaccinated and the rearing system, take 250 to 500 ml of water per 1,000 doses. The vaccine suspension is to be sprayed evenly over the appropriate number of
animals at a distance of 30 - 40 cm with a regular spraying apparatus, preferably when the animals sit together under a dim light. The spray apparatus must be free from sediments, corrosion and traces of
disinfectants and ideally should be used for vaccination purposes only.

If applicable, reduce ventilation to prevent loss of spray.
For future layers and breeders please see section “Indications”.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (+2 °C to +8 °C).
Do not freeze.
Keep the vial in the outer carton in order to protect from light.
Shelf-life after reconstitution according to directions: 2 hours.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

Only vaccinate healthy birds.
In order to reduce the circulation of the vaccine strain, all susceptible animals on the site have to be vaccinated properly and preferably at the same time. The vaccine virus can spread to other susceptible species with which they have direct contact. It was shown that the spreading has negligible impact on turkeys, which together with chickens constitute the species that are most susceptible to avian rhinotracheitis virus.
Do not use in birds in lay and/or within 4 weeks before the onset of the laying period.
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with vaccines against infectious bronchitis containing strain H120 and against Newcastle disease containing strains Clone 30 or C2 and infectious bronchitis vaccine (strain IB Ma 5) when given on day 1 (the efficacy of the IB Ma5 vaccine has not been investigated).
MSD’s live vaccine against Gumboro disease (infectious bursal disease) containing the D78 strain can be given 7 days after Nobilis Rhino CV.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above
A decision to use this vaccine before or after any other veterinary product therefore needs to be made on a case by case basis.
Administration of tenfold the maximum dose by the recommended routes has not resulted in any other effect on the target species than those described above.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

For animal treatment only.
To be supplied only on veterinary prescription.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Pack sizes
1, 2, 5, 10, 20 or 50 vials of 250, 500, 1,000, 2,500, 5,000, 10,000 or 25,000 doses.
Not all pack sizes may be marketed.

UK only
Vm 01708/4505
POM-V
To be supplied only on veterinary prescription.

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24
Ireland

Approved 14 August 2020