PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box/500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis REO Inac

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose (0.5 ml) contains: Inactivated reovirus (strains 1733 & 2408) inducing ≥7.4 $\log_2$ ELISA units

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

500 ml (1,000 doses)

5. TARGET SPECIES

Target species: chickens (breeding birds).

6. INDICATION(S)

For the active immunisation of parent birds for the passive immunisation of their progeny, to reduce mortality and clinical signs of disease caused by avian reoviruses. Active immunity develops in the parent within 4 weeks, and offspring born at any stage of the subsequent laying period will have passive immunity against reovirus infections for protection during the susceptible period in the early phase of life.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route of administration: IM or SC injection.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Expiry end of: {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

Allow to reach ambient temperature before use (15 °C - 25 °C)
Shake vigorously before and periodically during use.
Once opened, use within 3 hours.
Keep the bottle in the outer carton.
Disposal: read package leaflet.

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]

For animal treatment only.

POM-V

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:
MSD Animal Health UK Limited
Walton Manor
Walton, Milton Keynes
MK7 7AJ

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4329
POM-V
To be supplied only on veterinary prescription.

17. MANUFACTURER'S BATCH NUMBER

Batch No: {number}

Inactivated reovirus vaccine (strains 1733 & 2408) inducing ≥7.4 $\log_2$ ELISA units per dose (0.5 ml) in an oil adjuvanted emulsion for I.M. or S.C. injection to chickens.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Label/500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis REO Inac

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose (0.5 ml) contains: Inactivated reovirus (strains 1733 & 2408) inducing ≥7.4 log_2 ELISA units.

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

500 ml (1000 doses)

4. ROUTE(S) OF ADMINISTRATION

Route of administration: SC or IM injection.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch No.: {number}

7. EXPIRY DATE

Expiry end of: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
To be supplied only on veterinary prescription.
Target species: chickens (breeding birds).
Keep out of sight and reach of children.
Accidental injection is dangerous. Read the leaflet before use.
Store in a refrigerator. Do not freeze. Protect from light. Once opened, use within 3 hours. Allow to reach ambient temperature before use (15 °C - 25 °C). Shake vigorously before and periodically during use.

MA holder:
MSD Animal Health UK Limited
Walton Manor
Walton, Milton Keynes
MK7 7AJ
POM-V
Vm 01708/4329

PACKAGE LEAFLET FOR:

Nobilis REO Inac

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

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis REO Inac, Emulsion for injection

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

White to nearly white oily emulsion.
One dose (0.5 ml) contains:
Inactivated reovirus strains 1733 & 2408 inducing ≥ 7.4 $\log_2$ ELISA units.
Liquid paraffin as an excipient.

4. INDICATION(S)

For the active immunisation of parent birds for the passive immunisation of their progeny, to reduce mortality and clinical signs of disease caused by avian reoviruses. Active immunity develops in the parent within 4 weeks, and off spring born at any stage of the subsequentv laying period will have passive immunity against reovirus infections for protection during the susceptible period in the early phase of life.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

It is very common that a slight transient swelling (resolved within 3 weeks) may be felt in 50%
of the vaccinated birds at the site of vaccination.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (breeding birds).

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

Intramuscular or subcutaneous use.
The vaccine Nobilis REO Inac should be given to chickens (breeding birds) around 10–20 weeks of age but not less than 4 weeks before the expected onset of lay.
Dose of: 0.5 ml should be injected intramuscularly into the thigh or chest muscle or subcutaneously into the back of the neck, using a medium sized needle (20g x 1/2“).
For an optimal response in chickens (breeding birds) not primed by field virus, two vaccinations should be given approximately 6 weeks apart.

9. ADVICE ON CORRECT ADMINISTRATION

The vaccine may occasionally separate into two layers on storage. This in no way affects its potency, but the vaccine should be shaken vigorously before and during use to ensure a good emulsification.
An automatic injection system, incorporating a means to prevent back flushing and hence possible contamination of the vaccine, should be used to administer the vaccine.
Ensure that vaccination equipment is clean and sterile before use. Do not use vaccination equipment with rubber parts as the excipient may damage certain types of rubber.
Allow to reach ambient temperature before use (15°C - 25°C).

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2°C - 8°C) Do not freeze. Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton.
Keep the bottle in the outer carton.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Vaccinate healthy birds only.
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 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.
Lay:
Do not use in birds in lay and within 4 weeks before the onset of lay.
Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with other Intervet inactivated oil emulsion vaccines, containing the avian infectious bronchitis (IB), Gumboro disease (GD), Newcastle disease (ND), turkey rhinotracheitis (TRT) and/or egg drop syndrome (EDS) antigens.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product apart from the products listed above. 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 (symptoms, emergency procedures, antidotes):
Not different from single dose.
Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

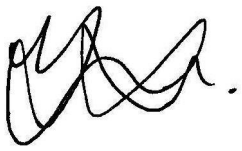
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2020

15. OTHER INFORMATION

For animal treatment only.
Package size: 500 ml (1,000 doses).
POM-V
To be supplied only on veterinary prescription.
Vm 01708/4329
Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24



Approved: 03 July 2020