ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX (50, 100 and 250 mL presentations)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nuflor Minidose 450 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 mL of the solution for injection contains 450 mg florfenicol and 350 mg N-methylpyrrolidone.

3. PACKAGE SIZE

50 mL
100 mL
250 mL

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous and intramuscular use.

7. WITHDRAWAL PERIODS

Meat and offal: Subcutaneous use (at 40 mg/kg body weight, once): 64 days.
Intramuscular use (at 20 mg/kg body weight, twice): 37 days.

Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the vial in the outer carton in order to protect from light.

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 OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3026

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VIAL (label for the 100 and 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nuflor Minidose 450 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 mL of the solution for injection contains 450 mg florfenicol and 350 mg N-methylpyrrolidone.

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Subcutaneous and intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Meat and offal: Subcutaneous use (at 40 mg/kg body weight, once): 64 days.
Intramuscular use (at 20 mg/kg body weight, twice): 37 days.

Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL (50 ml presentations)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nuflor Minidose

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

450 mg/ml Florfenicol

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nuflor Minidose 450 mg/ml solution for injection for cattle

2. Composition

The solution for injection contains 450 mg florfenicol and 350 mg N-methylpyrrolidone per ml.
Clear, colourless to yellow solution for injection.

3. Target species

Cattle.

4. Indications for use

Preventive and therapeutic treatment of respiratory tract infections in cattle due to *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* susceptible to florfenicol. The presence of the disease in the herd should be confirmed before administering preventive treatment.

5. Contraindications

Do not use in adult bulls intended for breeding purposes.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:
The product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.
Do not use where resistance to florfenicol or other amphenicols is known to occur.
Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to florfenicol and other amphenicols.
The prolonged or repeated use of the veterinary medicinal product should be avoided by improving farming management practices, cleaning and disinfection measures and eliminating any stress condition.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken to avoid accidental self-injection. In case of self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid direct contact with skin, mouth and eyes. Wash hands after treatment.

Laboratory studies in rabbits and rats with the excipient N-methylpyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

The veterinary medicinal product may cause hypersensitivity (allergy) in some people. People with hypersensitivity to florfenicol should avoid contact with the veterinary medicinal product.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in cattle during pregnancy, lactation, lay or in animals intended for breeding. Studies in laboratory animals have not been revealed any evidence of embryo- or foetotoxic potential for florfenicol. Laboratory studies in rabbits and rats with the excipient N-methylpyrrolidone have shown evidence of foetotoxic effects.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:
Do not use in adult bulls intended for breeding.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
No information available.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site pain[1,2,3], Injection site swelling[1,4], Injection site inflammation [1,5], Injection site lesion[1,5]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Reduced food intake[6]; Soft stool[2,6]

[1] After injection of the product at the maximum recommended volume of 10 mL per injection site
[2] Transient
[3] Lasting for some days
[4] Lasting up to 61 days after subcutaneous and up to 24 days after intramuscular injection
[5] Seen at necropsy and lasting for 37 days after intramuscular injection
[6] Quick and complete recovery upon termination of treatment

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 marketing authorisation holder or 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, routes and method of administration

Subcutaneous use: 40 mg/kg body weight (4 ml/45 kg) to be administered once only.
Intramuscular use: 20 mg/kg body weight (2 ml/45 kg) to be administered twice 48 hours apart.

The injection should only be given in the neck. The dose volume given at any one injection site should not exceed 10 ml.

To ensure correct dosage body weight should be determined as accurately as possible to avoid underdosing.

9. Advice on correct administration

Swab septum before removing each dose. Use a dry, sterile needle and syringe.
For 250 ml vials, do not broach the vial more than 25 times.

10. Withdrawal periods

Meat and offal: Subcutaneous use (at 40 mg/kg body weight, once): 64 days.
Intramuscular use (at 20 mg/kg bodyweight, twice): 37 days.

Not authorised for use in animals producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Package sizes:
1 vial of 50 ml in a cardboard box
1 vial of 100 ml in a cardboard box
1 vial of 250 ml in a cardboard box
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

January 2024

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Intervet International GmbH
Feldstrasse 1A
85716 Unterschleissheim
Germany

TriRx Segré
La Grindolière
Zone Artisanale
Segré
49500 Segré-en-Anjou Bleu
France

Vet Pharma Friesoythe GmbH
Sedelsberger Strasse 2 – 4
26169 Friesoythe
Germany

Contact details to report suspected adverse reactions:

Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

Distributor in Northern Ireland:

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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 28 April 2024