LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box for the 50, 100 and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR 300 mg/ml solution for injection for cattle and sheep
Florfenicol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Florfenicol 300 mg

3. PHARMACEUTICAL FORM

Clear, light yellow to straw-coloured, somewhat viscous solution
Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle and sheep.

6. INDICATION(S)

Not applicable for the outer package.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Meat and offal

Cattle:	IM use (20 mg/kg bodyweight, twice):	30 days.
	SC use (40 mg/kg bodyweight, once):	44 days.
Sheep:		39 days.

Milk
Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days.
Once opened, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Do not refrigerate.
Protect from frost.

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

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4574

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Label for the 100 and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR 300 mg/ml solution for injection for cattle and sheep
Florfenicol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Florfenicol 300 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle and sheep.

6. INDICATION(S)

Not applicable for the immediate package.

7. METHOD AND ROUTES OF ADMINISTRATION

Treatment: Intramuscular and subcutaneous use.
Metaphylaxis: Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Meat and offal

Cattle:	IM use (20 mg/kg bodyweight, twice):	30 days.
	SC (40 mg/kg bodyweight, once):	44 days.
Sheep:		39 days.

Milk

Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

9. SPECIAL WARNINGS

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the immediate packaging: 28 days.
Once opened, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Do not refrigerate.
Protect from frost.

12. SPECIAL 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

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 01708/4574

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for the 50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR 300 mg/ml solution for injection for cattle and sheep
Florfenicol

2. QUANTITY OF THE ACTIVE SUBSTANCES

Each 1 ml contains:
Florfenicol 300 mg

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

IM or SC use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal

Cattle:	IM (20 mg/kg bodyweight, twice):	30 days.
	SC (40 mg/kg bodyweight, once):	44 days.
Sheep:		39 days.

Milk:
Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

6. BATCH NUMBER

<Batch> <Lot> <BN> {number}

7. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days
Once opened, use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

NUFLOR 300 mg/ml solution for injection for cattle and sheep

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 Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
TriRx Segré
La Grindolière
Zone Artisanale
Segré
49500 Segré-en-Anjou Bleu
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR 300 mg/ml solution for injection for cattle and sheep
Florfenicol

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each 1 ml contains:
300 mg florfenicol
250 mg N-methyl-2-pyrollidone

Clear, light yellow to straw-coloured, somewhat viscous solution.

4. INDICATIONS

Cattle:
Diseases caused by florfenicol susceptible bacteria.
Metaphylactic and therapeutic treatment of respiratory tract infections in cattle due to *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni*. The presence of the disease in the herd should be established before metaphylactic treatment.

Sheep:
Treatment of ovine respiratory tract infection due to *Mannheimia haemolytica* and *Pasteurella multocida* susceptible to florfenicol.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Cattle:
A decrease in food consumption and transient softening of the faeces may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment. Intramuscular and subcutaneous administration may cause inflammatory lesions at the injection site which may persist for 14 days. In very rare cases, anaphylactic shock has been reported in cattle.

Sheep:
A decrease in food consumption may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment.
Intramuscular administration may cause inflammatory lesions at the injection site which may persist up to 28 days. Typically, these are mild and transient.

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

7. TARGET SPECIES

Cattle and sheep.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

For treatment
Cattle:
Intramuscular use: 20 mg/kg bodyweight (1 ml/15 kg) to be administered by intramuscular injection twice 48 hours apart using a 16 gauge needle.
Subcutaneous use: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once only using a 16 gauge needle.

Sheep:
Intramuscular use: 20 mg /kg bodyweight (1 ml/15 kg bodyweight) to be administered daily for three consecutive days.
Pharmacokinetic studies showed that mean plasma concentrations remain above MIC_{90} (1 µg/ml) for up to 18 hours after administration of the product at the recommended treatment dose. The pre-clinical data provided supported the recommended treatment interval (24 hours) for target pathogens with MIC up to 1 µg/ml.

For metaphylaxis
Cattle:
Subcutaneous use: 40 mg/kg bodyweight (2ml/15kg) to be administered once only using a 16 gauge needle.

9. ADVICE ON CORRECT ADMINISTRATION

The dose volume given at any one injection site should not exceed 10 ml for cattle and 4 ml for sheep.
The injection should only be given in the neck.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
Swab septum before removing each dose. Use a dry sterile needle and syringe.
The vials should not be broached more than 20 times. User should therefore select the most appropriate vial size according to the target species to be treated.
When treating groups of animals at the same time, use of a draw-off needle in the vial stopper is recommended to avoid excess stopper broaching. The draw-off needle should be removed after treatment.

10. WITHDRAWAL PERIOD

Meat and offal:

Cattle:	IM (20 mg/kg bodyweight, twice):	30 days.
	SC (40 mg/kg bodyweight, once):	44 days.
Sheep:		39 days.

Milk:
Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C.
Do not refrigerate.
Protect from frost.

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

12. SPECIAL WARNINGS

Special warnings for each target species:
None.

Special precautions for use in animals:
The product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.
The safety of the product has not been established in sheep younger than 7 weeks of age.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to propylene glycol and polyethylene glycols should avoid contact with the veterinary medicinal product. In case of accidental contact with skin or eyes, rinse immediately with plenty of water.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of fetotoxic 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.

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

Overdose (symptoms, emergency procedures, antidotes):
Cattle:
No symptoms other than those described in section 6.

Sheep:After administration of 3 times the recommended dose or more a transient reduction in feed and water consumption has been observed. Additional effects included an increased incidence of lethargy, emaciation and loose faeces.
Head tilt was seen after administration of 5 times the recommended dose and was considered most likely a result of irritation at the injection site.

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

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

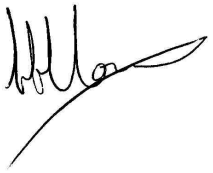
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

15. OTHER INFORMATION

Pack sizes: 50, 100 and 250 ml vials.
Not all pack sizes may be marketed.



Approved 08 March 2024