LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nifencol 300 mg/ml solution for injection for cattle and pigs
Florfenicol

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Florfenicol .....300 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml and 250 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous and intramuscular use in cattle, intramuscular use in pigs.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle:
Meat and offal by Intramuscular: 30 days
by Subcutaneous: 44 days

Milk: Not authorised for use in cattle producing milk for human consumption, including during the dry period.

Pigs:
Meat and offal: 18 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

Vetpharma Animal Health, S.L.
Les Corts, 23
08028 Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 32509/4011

17. MANUFACTURER'S BATCH NUMBER

Batch number

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{IMMEDIATE PACKAGE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nifencol 300 mg/ml solution for injection for cattle and pigs
Florfenicol

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Florfenicol .....300 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml and 250 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous and intramuscular use in cattle, intramuscular use in pigs.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period
Cattle:
Meat and offal by Intramuscular: 30 days
by Subcutaneous: 44 days

Milk: Not authorised for use in cattle producing milk for human consumption, including during the dry period.

Pigs:
Meat and offal: 18 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

Vetpharma Animal Health, S.L.
Les Corts, 23
08028 Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 32509/4011

17. MANUFACTURER'S BATCH NUMBER

Batch number

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Nifencol 300 mg/ml solution for injection for cattle and pigs

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

Marketing authorisation holder:
Vetpharma Animal Health, S.L.
Les Corts, 23
08028 Barcelona
Spain

Manufacturer responsible for batch release:
MEVET S.A.U
Pol. Ind. El Segre, P.410
25191 Lleida
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nifencol 300 mg/ml solution for injection for cattle and pigs
Florfenicol

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

Each ml contains

Active substance:
Florfenicol 300 mg

Excipients:
N-methylpyrrolidone……..250 mg

Clear slightly yellowish solution

4. INDICATION(S)

Cattle:
Metaphylaxis and therapeutic treatment of respiratory tract infections in cattle due to *Histophilus somni*, *Mannheimia haemolytica,* and *Pasteurella multocida,* susceptible to florfenicol.
The presence of the disease in the herd should be established before the product is used.

Pigs:
Treatment of acute outbreaks of respiratory disease caused by strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol.

5. CONTRAINDICATIONS

Do not use in adult bulls and boars intend for breeding purposes.
Do not use in cases of hypersensitivity to florfenicol or to any of the excipients.

6. ADVERSE REACTIONS

In 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.

Administration of the product by the intramuscular and subcutaneous routes may cause inflammatory lesions at injection site which persist for 14 days.

On very rare occasions, anaphylactic reactions have been reported in cattle.
In pigs, commonly observed adverse effects are transient diarrhoea and/or peri-anal and rectal erythema/oedema which may affect 50% of the animals. These effects can be observed for one week. Under field conditions approximately 30% of treated pigs presented with pyrexia (40°C) associated with either moderate depression or moderate dyspnea a week or more after administration of the second dose.

Transient swelling lasting up to 5 days may be observed at the site of injection. Inflammatory lesions at the injection site may be seen up to 28 days.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animals in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and pigs.

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

Cattle: Intramuscular or subcutaneous injection
Pig: intramuscular injection

Cattle:
Treatment
IM route: 20 mg florfenicol/kg bodyweight (1ml of the product /15kg) to be administered twice 48 hours apart using a 16 gauge needle.

SC route: 40 mg florfenicol/kg bodyweight (2ml of the product/15kg) to be administered once only using a 16 gauge needle.

Metaphylaxis
SC route: 40 mg florfenicol/kg bodyweight (2ml of the product/15kg) to be administered once only using a 16 gauge needle.

Pigs:
15 mg florfenicol/kg bodyweight (1 ml of the product / 20 kg) by intramuscular injection twice at 48 hour intervals using a 16-gauge needle.

9. ADVICE ON CORRECT ADMINISTRATION

The dose volume given at any one injection site should not exceed 10ml for both routes of administration (intramuscular and subcutaneous) in cattle and 3 ml in pigs. The injection should only be given in the neck in both target species.

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

It is recommended to treat animals in the early stages of disease and to evaluate the response to treatment within 48 hours after the second injection. If clinical signs of respiratory disease persist 48 hours after the last injection or if relapse occurs, treatment should be changed using another formulation or another antibiotic and continued until clinical signs have resolved
Swab septum before removing each dose. Use a dry sterile needle and syringe.
Do not broach the stopper of vial more than 25 times.

10. WITHDRAWAL PERIOD

Cattle:
Meat and offal: by Intramuscular: 30 days
by Subcutaneous: 44 days

Milk: Not authorised for use in cattle producing milk for human consumption, including during the dry period.

Pigs:
Meat and offal: 18 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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.
When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in

the container should be discarded should be worked out. This discard date should be written in the space provided on the label.
Shelf life after first opening the container: 28 days

12. SPECIAL WARNING(S)

Special precautions for use
This veterinary medicinal product does not contain an antimicrobial preservative.

Special precautions for use in animals
Do not administer to piglets of less than 2 kg.
Whenever possible, the veterinary medicinal product should be based on susceptibility testing. Official, national and regional antimicrobial policies should be taken into account when the product is used.

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 accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid skin or eye contact with the product. In case of contact with the skin or eyes, rinse the affected area immediately with plenty of water. Wash the hands after use.
People with known hypersensitivity to propylene glycol or polyethylene glycols should avoid contact with the veterinary medicinal product.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone 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.

Pregnancy and lactation
Studies in laboratory animals have not revealed any evidence of embryo- or foetotoxic potential for Florfenicol.

Cattle
The safety of the veterinary medicinal product has not been established in cattle 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
Pigs
The safety of the veterinary medicinal product has not been established in pigs 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):
In swine after administration of 3 times the recommended dose or more a reduction in feeding, hydration and weight gain has been observed.
After administration of 5 times the recommended dose or more vomiting has also been noted.

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 MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

15. OTHER INFORMATION

Cardboard box with 1 vial of 100ml.
Cardboard box with 1 vial of 250ml.

Not all pack sizes may be marketed.

Approved 23 January 2024