PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYCOFLOR, 300 mg/ml solution for injection for cattle and pigs

Florfenicol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Florfenicol 300 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml – 250 ml

5. TARGET SPECIES

Cattle, pigs

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

Intramuscular injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle:
Meat and offal: 34 days
Milk: Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 18 days

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the bottle 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

SP Veterinaria, S.A.
Ctra. Reus-Vinyols
Km 4.1 Aptdo. 60
43330 Riudoms
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 36967/4000

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYCOFLOR, 300 mg/ml solution for injection for cattle and pigs

Florfenicol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Florfenicol 300 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml – 250 ml

5. TARGET SPECIES

Cattle, pigs

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

Intramuscular injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle:
Meat and offal: 34 days
Milk: Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 18 days

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Once broached, use by
Shelf life after first opening the immediate packaging: 28 days

11. SPECIAL STORAGE CONDITIONS

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

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

SP Veterinaria, S.A.
Ctra. Reus-Vinyols
Km 4.1 Aptdo. 60
43330 Riudoms
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 36967/4000

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR:

MYCOFLOR, 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:
SP Veterinaria, S.A.
Ctra. Reus-Vinyols
Km 4.1 Aptdo. 60
43330 Riudoms
Spain

Manufacturer responsible for batch release:
Glass vials: KELA N.V., St. Lenaartseweg 48, 2320 Hoogstraten, Belgium
PP vials: SP VETERINARIA, Ctra. Reus-Vinyols, Km. 4,1, 43330 Riudoms, Tarragona, Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYCOFLOR, 300 mg/ml solution for injection for cattle and pigs

Florfenicol

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml of solution contains:

Active substance:
Florfenicol 300 mg

Excipients:
N-methyl pyrrolidone 200mg

Clear, light yellow to yellow solution.

4. INDICATIONS

Cattle: treatment of respiratory tract infections due to strains of *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni* susceptible to florfenicol.

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

5. CONTRAINDICATIONS

Do not use in adult bulls and boars intended for breeding purposes.
Do not use in piglets of less than 2 kg.

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer intravenously.
Do not use in known cases of resistance to the active substance.

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.
Administration of the product by the intramuscular route may cause inflammatory lesions at injection site which persist for 14 days.
On very rare occasions, anaphylactic reactions were observed.

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.
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.
Under field conditions approximately 30% of treated pigs presented with pyrexia (40°C) associated with either moderate depression or moderate dyspnoea a week or more after administration of the second dose.

The frequency of adverse reactions is defined using the following convention:
very common (more than 1 in 10 animals displaying adverse reactions 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 any other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, pigs

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

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The vial cannot be broached more than 25 times.

Cattle
IM injection of 20 mg/kg BW (1ml/15kg) into the neck muscle twice 48 hours apart. The volume administered per injection site should not exceed 10 ml. Subsequent injections must be given at different sites.

Pigs
IM injection of 15 mg/kg BW (1 ml/20 kg) into the neck muscle, twice, 48 hour apart. The volume administered per injection site should not exceed 3 ml. Subsequent injections must be given at different sites.

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, treatment should be changed using another formulation or another antibiotic and continued until clinical signs have resolved.
Ensure that the injection site is clean before administration of the product

9. ADVICE ON CORRECT ADMINISTRATION

Wipe the stopper before removing each dose. Use a dry, sterile syringe and needle.

10. WITHDRAWAL PERIOD

Cattle:
Meat and offal: 34 days
Milk: Not permitted for use in lactating animals producing milk for human consumption.

Pigs:
Meat and offal: 18 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the bottle 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. Shelf-life after first opening the immediate packaging: 28 days.
The expiry date refers to the last day of that month.

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 stopper must be cleaned before removing each dose. Use a dry, sterile syringe and needle.

Use of the product deviating from the instructions given in the leaflet may increase the prevalence of bacteria resistant to florfenicol and may decrease the effectiveness of treatment with other antimicrobials, due to the potential for cross-resistance.

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 direct contact with skin, mouth and eyes. If eye exposure occurs, flush eyes immediately with clean water. If skin exposure occurs, wash the affected area with clean water. If accidental ingestion occurs, rinse the mouth with plenty of water and seek medical advice immediately.
Wash hands after use.
People with known hypersensitivity to florfenicol should avoid contact with the veterinary medicinal product.
Do not smoke, eat or drink while handling this 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
The safety of the veterinary medicinal product has not been established in cattle and 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.

Interaction with other medicinal products and other forms of interaction:
No data available.

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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

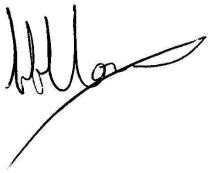
March 2024

15. OTHER INFORMATION

Vial sizes: 100 and 250 ml
Colourless Type II glass vials closed with bromobutyl rubber closures and an aluminium cap.
Polypropylene vials closed with bromobutyl rubber closures and an aluminium cap.

Vials are individually packed in carton box.

Not all pack sizes may be marketed.



Approved 08 April 2024