ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLORDOFEN 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

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTES OF ADMINISTRATION

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

8. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
Meat and offal by IM: 30 days
by SC: 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 WARNINGS, 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

Store below 25 °C.
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

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

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

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 28365/4007

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{IMMEDIATE PACKAGE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLORDOFEN 300 mg/ml Solution for injection for cattle and pigs

Florfenicol

2. STATEMENT OF ACTIVE SUBSTANCE

Each ml contains:
Florfenicol 300 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATIONS

Read the package leaflet before use.

7. METHODS AND ROUTES OF ADMINISTRATION

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

8. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
Meat and offal by IM: 30 days
by SC: 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 WARNINGS, 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

Store below 25 °C. 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

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 28365/4007

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
FLORDOFEN 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:
Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

Manufacturer responsible for the batch release:
Dopharma B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLORDOFEN 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

Clear slightly yellowish solution.

4. INDICATIONS

Cattle:
Treatment and metaphylaxis 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 established before metaphylaxis.

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 intended for breeding purposes.

Do not use in cases of hypersensitivity to the active substance 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 dyspnoea 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 treated 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 animal 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(S) OF ADMINISTRATION

Cattle: Intramuscular or subcutaneous injection
Pigs: Intramuscular injection

Cattle:
Treatment
IM route: 20 mg florfenicol / kg bodyweight (1 ml of the product / 15 kg) to be administered twice 48 hours apart using a 16-gauge needle.
SC route: 40 mg florfenicol / kg bodyweight (2 ml of the product / 15 kg) to be administered once only using a 16-gauge needle.

Metaphylaxis
SC route: 40 mg florfenicol / kg bodyweight (2 ml of the product / 15 kg) 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 10 ml 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 PERIODS

Cattle:
Meat and offal: by IM: 30 days
by SC: 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

Store below 25 °C.
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.

Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNINGS

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.
Use of product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official national and regional antimicrobial policies should be taken into account when the product is used.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the 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
People with known hypersensitivity to florfenicol or any of the excipients should avoid contact with the veterinary medicinal product.

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice taking the label or package leaflet with you to show 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.

Do not use the product if you know you are sensitive to propylene glycol or polyethylene glycols.

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 during pregnancy.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Pigs:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

It is not recommended to use the veterinary medicinal product in pigs during pregnancy and lactation.

Overdose (symptoms, emergency procedures, antidotes)
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.
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 PRODUCTS 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

15. OTHER INFORMATION

Box with 1 polypropylene vial of 250 ml.
Box with 1 colourless type II glass vial of 50 or 100 ml.
Box with 1 brown-coloured type II glass vial of 250 ml.

Not all pack sizes may be marketed.

Approved 18 October 2018