[Version 8.1,01/2017]

PACKAGE LEAFLET
PULMOVALL 300 mg/ml solution for injection for cattle, sheep 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 and manufacturer responsible for batch release:
MEVET S.A.U.
Polígono Industrial El Segre, p. 409-410,
25191 Lleida
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PULMOVALL 300 mg/ml solution for injection for cattle, sheep and pigs
Florfenicol

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

Each ml contains:

Active substance:
Florfenicol……..300 mg

Clear, yellowish solution, free from visible particles in suspension.

4. INDICATIONS

Cattle: Treatment and Metaphylaxis of bovine respiratory disease associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* susceptible to florfenicol. The presence of the disease in the group must be established before metaphylactic treatment.

Sheep**:** Treatment of ovine respiratory disease associated with *Mannheimia haemolytica* and *Pasteurella multocida* susceptible to florfenicol.

Pigs: Treatment of acute outbreaks of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol.

5. CONTRAINDICATIONS

Do not use in adult bulls, rams and boars 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.

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 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.
Alternatively, you can report via your national reporting system.

7. TARGET SPECIES

Cattle, sheep and pigs.

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

Administration route:
For intramuscular and subcutaneous use in cattle.
For intramuscular use in sheep and pigs.

For treatment:
Cattle**:**
Intramuscular use: 20 mg florfenicol/kg bodyweight (equivalent to 1 ml of the veterinary medicinal product/15 kg bodyweight) to be administered twice 48 hours apart.
Subcutaneous use: 40 mg florfenicol/kg bodyweight (equivalent to 2 ml of the veterinary medicinal product/15 kg bodyweight) to be administered once only
For both routes: use a 16-gauge needle. The dose volume given at any one injection site should not exceed 10 ml. The injection should only be given in the neck.

Sheep:
Intramuscular use: 20 mg florfenicol/kg bodyweight (equivalent to 1 ml of the veterinary medicinal product/15 kg bodyweight) to be administered daily for three consecutive days.
The volume administered per injection site should not exceed 4 ml.

Pig:

Intramuscular use: 15 mg florfenicol/kg bodyweight (equivalent to 1 ml of the veterinary medicinal product/20 kg bodyweight) by intramuscular injection into the neck muscle twice at 48-hour intervals using a 16-gauge needle.
The volume administered per injection site should not exceed 3 ml.
It is recommended to treat animals in the early stages of the disease and to evaluate the response to treatment within 48 hours after the last injection. If clinical signs of respiratory disease persist or increase, or if relapse occurs, treatment should be changed using another antibiotic and continued until clinical signs have resolved.

For metaphylaxis:
Cattle:
Subcutaneous use: 40 mg florfenicol/kg bodyweight (equivalent to 2 ml of the veterinary medicinal product/15 kg bodyweight) to be administered once only using a 16-gauge needle. The dose volume given at any one injection site should not exceed 10 ml.
The injection should only be given in the neck.

For all target species: To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

9. ADVICE ON CORRECT ADMINISTRATION

The stopper may be safely punctured up to 50 times.
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(S)

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.
Pig:		18 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.

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 the month.

Shelf life after first opening the container: 28 days.

12. SPECIAL WARNINGS

Special precautions for each target species:
None

Special precautions for use in animals:
Do not use in piglets of less than 2 kg.

The safety of the veterinary medicinal product has not been established in sheep younger than 7 weeks of age.

Use of the veterinary medicinal 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 florfenicol and may decrease the effectiveness of treatment with amphenicols due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product can cause hypersensitivity (allergy). People with known hypersensitivity to florfenicol, propylene glycol o to polyethylene glycols should avoid contact with the veterinary medicinal product.

This veterinary medicinal product contains N-Methylpyrrolidone which may be harmful for the unborn child; therefore, women of child-bearing age must be very careful to avoid exposure via spillage onto the skin or accidental self-injection when administering the veterinary medicinal product. If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the veterinary medicinal product.

Administer the veterinary medicinal product with caution 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. This veterinary medicinal product may cause skin and eye irritation. Avoid contact with skin or eyes. In case of accidental contact, wash immediately exposed area with plenty of clean water.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the physician the package leaflet or the label.

Other precautions:
Florfenicol is known to be toxic for terrestrial plants, cyanobacteria and groundwater organisms.

Pregnancy, Lactation and Lay:
Studies in laboratory animals with florfenicol have not revealed any evidence of teratogenic or foetotoxic effects. Laboratory studies with the excipient N-Methylpyrrolidone in rabbits and rats have shown evidence of teratogenic, foetotoxic, maternotoxic and reprotoxic effects.

Cattle and sheep: the effect of florfenicol on bovine and ovine reproductive performance and pregnancy has not been assessed. Do not use the product during pregnancy and lactation.

Pigs: the safety of the product in sows during pregnancy and lactation has not been demonstrated. Do not use the product during pregnancy and lactation.

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

Overdose (symptoms, emergency procedures, antidotes):

Cattle:
No symptoms other than those described in *Adverse reactions*.

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.

Pigs:
After administration of 3 times the recommended dose or more a reduction in feeding, water consumption 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

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product is dangerous for aquatic organisms (such as cyanobacteria). Do not contaminate surface waters or ponds with used product or containers.

Ask your veterinary surgeon or pharmacist 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

DD/MM/YYYY

15. OTHER INFORMATION

Pack sizes:
Carton box with 1 vial of 100 ml
Carton box with 1 vial of 250 ml
Carton box with 10 vials of 100 ml
Carton box with 15 vials of 250 ml

Not all pack sizes may be marketed.

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