VETERINARY MEDICINE
S4

Florkem®

Reg. No.: 13/17.1/10 (Act 101 of 1965)
Zambia Reg. No.: 346/719V (Act 3/2013)

SCHEDULING STATUS
S4

PROPRIETARY NAME (AND DOSAGE FORM)
FLORKEM® (solution for injection)

COMPOSITION
Each mℓ contains florfenicol 300 mg as the active ingredient.
The inactive ingredients are: diethylene glycol monoethyl ether, dimethylacetamide, macrogol 300.

PHARMACOLOGICAL CLASSIFICATION
C.17.1 Antibacterials

PHARMACOLOGICAL ACTION
Florfenicol is a synthetic, broad spectrum antibiotic effective against most Gram-negative and Gram-positive bacteria isolated from domestic animals.
Florfenicol acts by inhibiting bacterial protein synthesis at the ribosomal level and is thus bacteriostatic. However, *in vitro* activity tests have shown that florfenicol has bactericidal activity against the most commonly isolated bacterial pathogens involved in respiratory diseases:
- *Histophilus somni, Mannheimia haemolytica* and *Pasteurella multocida*, isolated from cattle.
- *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*, isolated from swine.
- *Arcanobacterium pyogenes* isolated from cattle and swine.
- *Mannheimia haemolytica* and *Pasteurella multocida*, isolated from sheep.

Acquired resistance to florfenicol is mediated by efflux pump resistance associated with a floR gene. Such resistance has not yet been identified in the target pathogens except for *Pasteurella multocida*. Cross resistance with chloramphenicol can occur. Resistance to florfenicol and other antimicrobials has been identified in the food-born pathogen *Salmonella typhimurium*.
For *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni*, the following breakpoints have been determined for florfenicol in bovine respiratory disease, susceptible: ≤ 2 µg/mℓ, intermediate 4 µg/mℓ, resistant ≥ 8 µg/mℓ.

INDICATIONS PER SPECIES
Diseases caused by florfenicol susceptible bacteria.

Cattle: **FLORKEM®** is indicated for the treatment and control of Bovine Respiratory Disease (BRD) associated with *Mannheimia haemolytica, Pasterella multocida, Mycoplasma bovis* and *Histophilus somni*. The metaphylactic use of **FLORKEM®** should be reserved for cattle at high risk of developing BRD associated with florfenicol sensitive bacteria.
FLORKEM® is indicated for the treatment bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fosobacterium necrophorum* and *Prevotella melaninogenica*.
Swine: Treatment of infections due to florefenicol sensitive bacteria and acute outbreaks of respiratory disease caused by strains of *Actinobacillus pleuropneumoniae, Pasteurella multocida* and *Mycoplasma hyopneumoniae*.
Sheep: Treatment of ovine respiratory disease (ORD) associated with *Mannheimia haemolytica* and *Pasteurella multocida*.

CONTRA-INDICATIONS
Do not use in adult bulls or boars intended for breeding purposes.
Do not use in cattle producing milk for human consumption.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

WARNINGS
Withdrawal period:
Cattle: Do not slaughter animals for human consumption within 30 days after the last intramuscular treatment.
Do not slaughter animals for human consumption within 44 days after subcutaneous treatment.
The effect of **FLORKEM®** on bovine reproductive performance and pregnancy has not been assessed.
Swine: Do not slaughter animals for human consumption within 21 days after last treatment.
Sheep: Do not slaughter animals for human consumption within 37 days after last treatment.
The effect of **FLORKEM®** on ovine reproduction performance has not been assessed.
The safety of **FLORKEM®** in sows and ewes during pregnancy and lactation has not been demonstrated.

Special Warnings:
Wipe the stopper before removing each dose. Use a dry sterile needle and syringe.
Do not use in piglets of less than 2 kg.
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.
This product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Special precautions to be taken by the person administering the veterinary medicinal product.
Care should be taken when handling the product to avoid accidental self injection. In case of accidental self injection, seek medical advice, and show the package insert or the label to the medical practitioner.
People with known hypersensitivity to the components of the formulation should avoid contact with the product.
Wash hands after handling the product.

SAFETY IN PREGNANCY AND LACTATION
Studies in laboratory animals have not revealed any evidence of embryo- foetotoxic potential for florfenicol. However, the safety of florfenicol on bovine, porcine and ovine reproductive performance and pregnancy and lactation has not been assessed. Use only according to the benefit / risk assessment by the responsible veterinarian.

DOSAGE AND DIRECTIONS FOR USE
Cattle: The injection should be given in the neck either by intramuscular or subcutaneous injection as follows:
Intramuscular injection: 20 mg florfenicol per kg body weight by i.e. 1 mℓ of **FLORKEM®** per 15 kg bodyweight, twice 48 hours apart.
Subcutaneous injection: 40 mg **FLORKEM®**/kg body mass administered as a single injection.
The volume administered per injection site should not exceed 10 mℓ.
Swine: 15 mg florfenicol per kg body weight by intramuscular injection into the neck (1 mℓ of **FLORKEM®** per 20 kg body weight) twice 48 hours apart. The volume administered per injection site should not exceed 3 mℓ.
Sheep: The recommended dose is 20 mg/kg (1 mℓ per 15 kg) by intramuscular injection into the neck once daily for 3 consecutive days. (Alternate between each side of the neck).
To ensure correct dosage body weight 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, treatment should be changed.

SIDE EFFECTS AND SPECIAL PRECAUTIONS
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 the injection site which may persist for 28 days.
Swine: Commonly observed side 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 up to one week.
Administration of the product by intramuscular route may cause inflammatory lesions at injection site which disappear within 21 days.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinarian.

KNOWN SIGNS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
In swine, after intramuscular administration of three 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.

IDENTIFICATION
Pale yellow to yellow clear solution.

PRESENTATION
Colourless type II glass vial: 20 mℓ, 50 mℓ, 100 mℓ, 250 mℓ and 500 mℓ packed in an outer cardboard carton.
Translucent multi-layer plastic vials: 50 mℓ; 100 mℓ, 250 mℓ and 500 mℓ packed in an outer cardboard carton.
The containers are closed with a red-brown chlorobutyl type II rubber stoppers and sealed with an aluminium cap covered with a green polypropylene top.

STORAGE INSTRUCTIONS
Store at or below 25 °C.
Keep out of reach of children and uninformed persons.
Use the contents of the bottle within 28 days following withdrawal of the first dose. Discard any unused solution.

REGISTRATION NUMBER
13/17.1/10 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Ceva Animal Health (Pty) Ltd
Co. Reg. No.: 1973/016009/07
P.O.Box 7707
Halfway House
1685
Tel.: +27 (0) 11 312 4088

DATE OF NOTIFICATION OF APPROVAL OF THIS SCIENTIFIC PACKAGE INSERT
25 November 2016

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NOT FLORKEM CLAS ZA	FLORKEM 250ML CLAS
400x160/FP35.5x160	AFRIQUE DU SUD
Recto	
CODE ARTICLE : A0804-02	ID : 80108
BLACK	CORPS : 9 pts

OLIVIER 10/08/23