VETERINARY MEDICINE. FOR ANIMAL USE ONLY.

PROPRIETARY NAME AND DOSAGE FORM:

Cyflor
Injection for Cattle & Swine

SCHEDULING STATUS:
S4

COMPOSITION:
Each 1,0 mℓ solution contains: Florfenicol 300,0 mg

PHARMACOLOGICAL CLASSIFICATION:
C 17.1 Antibacterials

PHARMACOLOGICAL ACTION:
Florfenicol is a synthetic, broad-spectrum antibiotic which acts by inhibiting bacterial protein synthesis at the ribosomal level.
Florfenicol is active against a wide range of aerobic and anaerobic Gram-negative and Gram-positive bacteria isolated from domestic animals.
In vitro activity has been shown in cattle against *Mannheimia haemolytica, Pasteurella multocida, Mycoplasma bovis, Histophilus somni, Escherichia coli, Salmonella* spp., *Moraxella* spp., *Klebsiella* spp., *Bacteroides* spp., *Fusobacterium* spp., *Trueperella pyogenes, Streptoccus agalactiae, Stretococcus dysgalactiae, Streptococcus uberis, Streptococcus zooepidemicus, Staphylococcus aureus, Staphylococcus epidermidis* and *Clostridium* spp.
In vitro testing has shown that florfenicol is active against the bacterial pathogens most commonly isolated in respiratory disease in pigs, including *Actinobacillus pleuropneumoniae, Pasteurella multocida* and *Mycoplasma hyopneumoniae. In vitro* sensitivity does not necessarily imply *in vivo* efficacy.

INDICATIONS:
Cattle (administration by intramuscular or subcutaneous injection):
Cyflor Injection is indicated for the treatment of bovine respiratory disease (BRD) (also known as shipping fever or transit fever) associated with bacteria susceptible to florfenicol, including *Mannheimia haemolytica, Mycoplasma bovis* and *Pasteurella multocida*, as well as bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Prevotella melaninogenica.*

Swine (pigs) (administration by intramuscular injection):
Cyflor Injection is indicated for the treatment of infections due to florfenicol-sensitive bacteria and for the treatment of respiratory infections caused by *Actinobacillus pleuropneumoniae, Pasteurella multocida* and *Mycoplasma hyopneumoniae.*

CONTRAINDICATIONS:
Do not use in cows producing milk for human consumption or in bulls intended for breeding purposes. Do not administer to boars intended for breeding.

WARNINGS AND SPECIAL PRECAUTIONS:
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.

Swine (pigs):
Do not slaughter animals for human consumption within 21 days after the last intramuscular treatment.

The safety of **Cyflor Injection** in sows during pregnancy and lactation has not been demonstrated.

DOSAGE AND DIRECTIONS FOR USE:
Cattle: The recommended dose is 20 mg / kg body mass (1 mℓ/ 15 kg) by intramuscular injection. Administer a total of two injections 48-hours apart using a 16 G needle.
Alternatively, administer by a single subcutaneous injection at a dose rate of 40 mg / kg body mass.
Do not administer more than 10 mℓ at each site.
The injection should be given only in the neck.
A clinical response was evident in most treated animals within 24-hours of initiating therapy.

Swine (pigs): The recommended dose is 15 mg / kg body mass (1 mℓ per 20 kg) by intramuscular injection into the neck muscle. Administer a total of two injections 48-hours apart using a 18 G needle. The volume administered per site of injection should not exceed 10 mℓ.

SIDE EFFECTS:
Decreased food consumption has been observed. The effect of administering **Cyflor Injection** with other medicinal products is not known.
Microsomal enzyme inhibition may occur.
In Cattle, subcutaneous administration of **Cyflor Injection** may occasionally result in swelling and hardness at the injection site, which are usually resolved within 31 days of the subcutaneous administration. A small local area of hardness may be present at the precise site of administration beyond 31 days, which will resolve eventually.
No injection site reactions were observed in cattle during clinical studies with **Cyflor Injection** following intramuscular administration; however, as with any intramuscular injection, injection site reactions such as swelling and hardness may occur.
In swine (pigs), diarrhoea and/or peri-anal erythema/oedema may occur transiently following treatment. No injection site reactions were noted in swine (pigs) during clinical studies with **Cyflor Injection**, following intramuscular administration. There have been reports of transient reactions, which may occasionally occur with minor swelling at the injection site, following intramuscular administration of florfenicol to swine (pigs). These swellings disappear completely within 21 days.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Gross overdose of **Cyflor Injection** can result in anorexia, pyrexia, vomiting, diarrhoea and slight ataxia which resolve within 2 weeks. Treatment is symptomatic and supportive.

IDENTIFICATION:
A clear, light yellow to straw-coloured solution.

PRESENTATION:
Clear Type 1 glass or clear HDPE vials containing 100 mℓ and 250 mℓ florfenicol solution.
100 mℓ glass and HDPE vials are closed with 20 mm Grey Bromobutyl bungs and sealed with 20 mm aluminium seals.
250 mℓ glass and HDPE vials are closed with 32 mm Grey Bromobutyl bungs and sealed with 32 mm aluminium caps with pull-off rings.
100 mℓ and 250 mℓ glass vials are packed in polyethylene protective sleeves, which are placed inside cardboard cartons.
100 mℓ and 250 mℓ HDPE vials are packed in cardboard cartons.

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 the withdrawal of the first dose.

REGISTRATION NUMBER:
11/17.1/09

Export countries:
Botswana: POM BOV2500016
Namibia: NS0 V21/17.1/1492

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