VETERINARY MEDICINE

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

Cyflor Injection for Cattle and Swine

COMPOSITION:
Each ml contains Florfenicol 300 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., *Arcanobacterium 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, also called shipping fever or transit fever associated with bacteria susceptible to florfenicol, including *Mannheimia haemolytica, Mycoplasma bovis* and *Pasteurella multocida* and for the treatment of bovine interdigital phlegmon (foot rot, acute interdigital nercrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Prevotella melaninogenica*.

Swine (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:
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.
Clinical response was evident in most treated animals within 24 hours of initiation of therapy.

Swine: 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:
Lowering of food consumption has been observed. The effect of administering **Cyflor Injection** with other medicine products is not known.
Microsomal enzyme inhabitation 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 noted in cattle during clinical studies with **Cyflor Injection**, following intramuscular administration, however, as with any intramuscular injection, injection site reactions of swelling and hardness may occur following the intramuscular administration of **Cyflor Injection.**
In Swine diarrhoea and/or peri-anal erythema/oedema may occur transiently following treatment. No injection site reactions were noted in swine 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. 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 50 ml, 100 ml, 250 ml or 500 ml florfenicol solution. 50 ml and 100 ml glass and HDPE vials are closed with 20 mm Grey Bromobutyl bungs and sealed with 20 mm aluminium seals. 250 ml and 500 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, 250 ml and 500 ml glass vials are packed in polyethylene protective sleeves, which are placed inside cardboard cartons. 50 ml glass and 50 ml, 100 ml, 250 ml and 500 ml HDPE vials are packed in cardboard cartons.

STORAGE INSTRUCTIONS:
Store at or below 25 °C.
Keep out of reach and sight of children.
Use the contents of the bottle within 28 days following the withdrawal of the first dose.

REGISTRATION NUMBER:
Cyflor Injection: 11/17.1/09

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
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