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:
Biotech Laboratories (Pty) Ltd
Ground Floor, Block K West
Central Park, 400 16th Road,
Midrand, Gauteng, 1685

Marketed by:
Biotech Laboratories (Pty) Ltd
Tel: (011) 848 3050
Fax: (011) 848 3065
Email: info@biotechlabs.co.za
www.biotechlabs.co.za

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VETERINÊRE MEDISYNE

SKEDULERINGSTATUS: S4

EIENDOMSNAAM EN DOSEERVORM:

Cyflor Injection for Cattle and Swine

SAMESTELLING:
Elke ml bevat Florfenikol 300 mg.

FARMAKOLOGIESE KLASSIFIKASIE:
C 17.1 Antibakteriese middel

FARMAKOLOGIESE WERKING:
Florfenikol is 'n sintetiese, breë spektrum antibiotika wat bakteriële proteïensintese op ribosomale vlak inhibeer.
Florfenikol is aktief teen 'n wye verskeidenheid aerobiese en anaerobiese Gram-negatiewe en Gram-positiewe bakterieë wat vanuit plaasdiere geïsoleer is.
In vitro aktiwiteit is aangetoon in beeste teen *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* en *Clostridium* spp.
In vitro toetse het aangetoon dat florfenikol aktief is teen die algemeenste bakteriële patogene wat tydens respiratoriese siektetoestande in varke geïsoleer is, insluitend *Actinobacillus pleuropneumoniae, Pasteurella multocida* en *Mycoplasma hyopneumoniae. In vitro* sensitiwiteit beteken nie noodwendig *in vivo* effektiwiteit nie.

INDIKASIES:
Beeste (binnespierse of onderhuidse toediening):
Cyflor Inspuiting word aangedui vir die behandeling van beesasemhalingsiekte, ook bekend as verskepingskoors of vervoerkoors ("transit fever"), wat geassosieer word met bakterieë wat sensitief is vir florfenikol, insluitend *Mannheimia haemolytica, Mycoplasma bovis* en *Pasteurella multocida,* asook vir die behandeling van interdigitale toestande in beeste (vrotpootjie, akute interdigitale nekrobasillose, aansteeklike pododermatitis) wat geassosieer word met *Fusobacterium necrophorum* en *Prevotella melaninogenica.*

Varke (binnespierse toediening):
Cyflor Inspuiting word aangedui vir die behandeling van infeksies wat veroorsaak is deur florfenikol sensitiewe bateriеë en vir die behandeling van respiratoriese infeksies wat veroorsaak is deur *Actinobacillus pleuropneumoniae, Pasteurella multocida* en *Mycoplasma hyopneumoniae.*

KONTRAINDIKASIES:
Moet nie gebruik word in beeste wat melk vir menslike gebruik produseer of in bulle wat vir teel doeleindes aangewend word nie.
Moet nie gebruik word in varkbere wat vir teel doeleindes aangewend word nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
Beeste:
Moet nie diere vir menslike verbruik binne 30 dae na die laaste binnespierse behandeling slag nie.
Moet nie diere vir menslike verbruik binne 44 dae na die laaste onderhuidse behandeling slag nie.

Varke:
Moet nie diere vir menslike verbruik binne 21 dae na die laaste binnespierse behandeling slag nie.

Die veiligheid van **Cyflor Inspuiting** in dragtige en lakterende soë is nie bevestig nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Beeste: Die aanbevole dosis is 20 mg/kg liggaamsmassa (1 ml/15 kg) deur middel van 'n binnespierse inspuiting. 'n Totaal van twee inspuitings moet 48 uur uitmekaar toegedien word met 'n 16 G naald.
Alternatiewelik kan 'n enkel dosis van 40 mg/kg liggaamsmassa onderhuids toegedien word.
Moet nie meer as 10 ml op dieselfde area toedien nie.
Die inspuiting behoort slegs in die nek toegedien te word.
'n Kliniese respons was sigbaar in die meeste diere wat behandel is binne 24 uur na aanvang van terapie.

Varke: Die aanbevole dosis is 15 mg/kg liggaamsmassa (1 ml/20 kg) deur middel van 'n binnespierse inspuiting in die nekspier. 'n Totaal van twee inspuitings moet 48 uur uitmekaar toegedien word met 'n 18 G naald. Die volume wat toegedien word mag nie meer as 10 ml per toedieningsarea oorskry nie.

NEWE EFFEKTE:
'n Afname in voedsel inname is waargeneem. Die effek van gelyktydige toediening van **Cyflor Inspuiting** met ander medisinale produkte is onbekend.
Mikrosomale ensiemonderdrukking kan voorkom.
In beeste kan onderhuidse toediening van **Cyflor Inspuiting** soms swelling en hardheid by die area van inspuiting veroorsaak, wat gewoontlik binne 31 dae na die onderhuidse toediening opklaar. 'n Klein lokale area van hardheid kan vir langer as 31 dae by die spesifieke plek van inspuiting voorkom, wat uiteindelik sal opklaar.
In beeste is geen reaksies by die inspuitingsareas opgemerk tydens kliniese studies met **Cyflor Inspuiting** na binnespierse toediening nie. Soos met enige binnespierse toediening kan daar wel swelling en hardheid voorkom by die plek van inspuiting na toediening van **Cyflor Inspuiting**.
In varke kan verbygaande diarree en/of peri-anale eriteem/edeem voorkom na behandeling. Geen reaksies is by die inspuitingsareas opgemerk tydens kliniese studies met **Cyflor Inspuiting** na binnespierse toediening nie. Daar was gevalle van verbygaande reaksies, wat somtyds kan voorkom met ligte swelling by die inspuitingsarea na binnespierse toediening met florfenikol aan varke. Die swelling het binne 21 dae geheel en al verdwyn.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Ernstige oordosering van **Cyflor Inspuiting** kan anoreksie, koors, naarheid, diaree en ligte ataksie veroorsaak, wat binne 2 weke sal opklaar. Die behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
'n Helder, liggeel tot strooi-kleurige oplossing.

AANBIEDING:
Helder Tipe 1 glas of helder HDPE flessies wat 50 ml, 100 ml, 250 ml of 500 ml florfenikol oplossing bevat.
50 ml en 100 ml glas en HDPE flessies word met 20 mm Grys Bromobutiel stoppers toegemaak en met 20 mm aluminium seëls geseël.
250 ml en 500 ml glas en HDPE flessies word met 32 mm Grys Bromobutiel stoppers toegemaak en met 32 mm aluminium doppies met aftrek ringe geseël.
100 ml, 250 ml en 500 ml glas flessies word in poliëtileen beskermende omhulsels verpak, wat dan in kartondose geplaas word.
50 ml glas en 50 ml, 100 ml, 250 ml en 500 ml HDPE flessies word in kartondose verpak.

BERGINSAANWYSINGS:
Bewaar teen of benede 25 °C.
Hou buite bereik en sig van kinders.
Gebruik die inhoud van die flessie binne 28 dae na die ontrekking van die eerste dosering.

REGISTRASIE NOMMER:
Cyflor Inspuiting: 11/17.1/09

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
Biotech Laboratories (Edms) Bpk
Grond Vloer, Blok K Wes, Central Park
400 16de Straat, Midrand, Gauteng, 1685

Bemark deur:
Biotech Laboratories (Edms) Bpk
Tel: (011) 848 3050
Faks: (011) 848 3065
Epos: info@biotechlabs.co.za
www.biotechlabs.co.za

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