Professional information for

KELAFLO 300 mg/mL

VETERINARY MEDICINE

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

KELAFLO 300 mg/mL, solution for injection for cattle and pigs.

COMPOSITION

Active ingredient

300 mg florfenicol per mL

Other ingredients

Glycerol formal and *N*-methylpyrrolidone.

PHARMACOLOGICAL CLASSIFICATION

C 17.1.5 Antibacterials, amphenicol

PHARMACOLOGICAL ACTION

Pharmacokinetic properties

Florfenicol is characterised by a high bioavailability, good tissue penetration and rapid elimination. Florfenicol appears to be well distributed throughout the body, including achievement of therapeutic levels in the internal organs, skeletal muscle, milk, synovial fluid, and to a lesser extent aqueous humor and spinal fluid.

The main elimination route of florfenicol was via urine. The parent compound represented the major fraction of the radioactivity (45 to 60 %) in urine, followed by florfenicol amine (11,2 to 17 %), florfenicol oxamic acid (less than 10 %), florfenicol alcohol (1,10 %), monochloroflorfenicol (1,90 %) and the remaining part of radioactivity being represented by a small percentage of three unknown compounds. In faeces, the same metabolites were found.

Pharmacodynamic properties

Florfenicol is a synthetic, broad-spectrum antibiotic that inhibits protein synthesis of bacteria 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 was shown in cattle against the following: *Mannheimia haemolytica, Pasteurella multocida, Mycoplasma bovis, Histophilus somni, Escherichia coli, Salmonella* spp., *Moraxella* spp., *Klebsiella* spp., *Bacteroides* spp., *Fusobacterium* spp., *Trueperella pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, *Streptococcus zooepidemicus*, *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Clostridium* spp.

Laboratory tests have shown that florfenicol has a bactericidal activity against *Manheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni*.

In vitro testing has shown that florfenicol has activity 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 indicate *in vivo* efficacy.

INDICATIONS

Cattle:

Treatment of respiratory disease, also called shipping fever or transit fever, associated with microorganisms sensitive to florfenicol, including *Mannheimia haemolytica*, *Mycoplasma bovis* and *Pasteurella multocida*, and for treatment of interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Prevotella melaninogenica*.

Metaphylaxis: for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Mycoplasma bovis*, *Pasteurella multocida* and *Histophilus somni*.

Pigs:

Treatment of infections associated with microorganisms sensitive to florfenicol and for the treatment of respiratory diseases caused by *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and *Mycoplasma hyopneumoniae*.

CONTRAINDICATIONS

Do not use in cows producing milk for human consumption.

Do not use in bulls and boars intended for breeding purposes.

WARNINGS

WITHDRAWAL PERIOD

Cattle:

Do not slaughter animals for human consumption within 34 days after the last intramuscular treatment.

Do not use in cows producing milk intended for human consumption.

Pigs:

Do not slaughter animals for human consumption within 20 days after last treatment.

PREGNANCY, LACTATION OR LAY

Safety during pregnancy and lactation in cows and sows 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 2 injections 48 hours apart using a 18 G needle.

Do not administer more than 10 mL at each injection site.

The injection should only be given in the neck.

A clinical response was noticeable in most treated animals within 24 hours after initiation of therapy.

Pigs:

The recommended dose is 15 mg/kg body mass (1 mL/20 kg) by intramuscular injection into the neck muscle. Administer a total of 2 injections 48 hours apart using a 18 G needle. The volume administered per site of injection should not exceed 10 mL.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

- Lowering of food consumption has been observed.
- The effect of simultaneous administration with other products is unknown.
- Microsomal enzyme inhibition may occur.
- In swine, diarrhoea and/or peri-anal erythema/oedema may occur transiently following treatment. A transient reaction may occasionally occur with minor swelling at the injection site. These swellings disappear completely within 21 days.

KNOWN SIGNS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT

A large overdose may cause anorexia, pyrexia, vomiting, diarrhoea and sligth ataxia which resolves within 2 weeks. Treatment is symptomatic and supportive.

IDENTIFICATION

Clear, light yellow to yellow solution.

PRESENTATION

Vial sizes: 100 mL and 250 mL.

Colourless Type II glass vials closed with bromobutyl rubber closures and aluminium caps.

Vials are individually packed in a carton box.

Six, ten or twelve of these are grouped as a clinical pack.

Not all pack sizes may be marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Do not freeze or refrigerate.

Keep the vial in the outer carton until required for use.

KEEP OUT OF REACH OF CHILDREN AND UNINFORMED PERSONS.

Use the contents of the vial within 28 days following withdrawal of the first dose. Discard any unused solution.

REGISTRATION NUMBER

20/14

NAME AND BUSINESS ADDRESS OF HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd

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DATE OF NOTIFICATION OF APPROVAL OF THIS SCIENTIFIC PACKAGE INSERT

01 April 2025