Tilflotrim

50 mg/ml Tilmicosin + 25 mg/ml Levofloxacin + 25 mg/ml Trimethoprim
Oral solution for poultry and pigs

COMPOSITION PER ML

Tilmicosin (as tilmicosin phosphate) ……..…….. 50 mg
Levofloxacin ……..…….. 25 mg
Trimethoprim……..…….. 25 mg
Excipients (sodium formaldehyde sulfoxylate, EDTA disodium salt, acetic acid) and solvent (water).
Light yellow to dark yellow liquid. Small amount of a sediment may form during storage.

INDICATIONS FOR USE

For the treatment of infections associated with micro-organisms susceptible to active ingredients in poultry and pigs. Tilflotrim is used for the treatment of respiratory, gastrointestinal and urogenital diseases; mycoplasmosis, colibacillosis, pasteurellosis, salmonellosis, staphylococcal and streptococcal infections, necrotic enteritis, dysentery, Haemophilus infection, ornithobacteriosis, chlamydiosis, and other infections.

DOSAGE AND ADMINISTRATION

For oral administration via drinking water:
- Poultry (broiler chickens, replacement chickens, turkeys, geese, ducks): 0,25-0,5 ml per kg body weight for 3 days. If administered to a group, the dose is 1-2 L per ton of drinking water for 3-5 days.
- Pigs: 0,25-0,5 ml per kg body weight for 3-5 days. If administered to a group, the dose is 1-2 L per ton of drinking water for 3 days.

Medicated drinking water should be freshly prepared every 24 hours. No other source of drinking water should be available during the medication period. When preparing the medicated solution the product is added to the water.

PHARMACOLOGICAL PROPERTIES

Tilmicosin, levofloxacin, and trimethoprim provide a synergistic effect and broad antimicrobial activity. The combination of active ingredients is highly active against Gram-negative bacteria (Mycoplasma spp., Campylobacter spp., Enterobacter spp., Escherichia coli, Haemophilus spp., Klebsiella spp., Pasteurella spp., Proteus spp., Pseudomonas spp., Salmonella spp., Serratia spp., Rickettsia spp., Ornithobacterium rhinotracheale) and Gram-positive bacteria (Staphylococcus spp., Streptococcus spp., Enterococcus spp., Mycobacterium spp., Clostridium spp., Listeria monocytogenes, Corynebacterium spp.), and Chlamydia spp., Brachyspira hyodysenteriae.
Tilmicosin is a semi-synthetic antibiotic of the macrolide group. It has a wide spectrum of activity against Gram-positive bacteria and certain Gram-negative microorganisms. Macrolides inhibit protein synthesis by reversibly binding to the 50S ribosomal subunit. Bacterial growth is inhibited by induction of the separation of peptidyl transfer RNA from the ribosome during the elongation phase. Tilmicosin exhibits also anti-inflammatory and immunomodulatory effects.
Levofloxacin is a broad-spectrum, third-generation fluoroquinolone antibiotic with broad spectrum of activity against most aerobic Gram-positive and Gram-negative organisms and demonstrates moderate activity against anaerobes. Levofloxacin exerts its antimicrobial activity via the inhibition of two key bacterial enzymes: DNA gyrase (topoisomerase II) and topoisomerase IV. The inhibition of these enzymes by levofloxacin occurs via complexation with the topoisomerase enzymes. The result is a blockade of DNA replication, thus inhibiting cell division and resulting in cell death. Levofloxacin overcomes bacterial drug resistance to the older quinolones, including enrofloxacin.
Trimethoprim, as a derivative of diaminopyrimidine. It blocks bacterial production of tetrahydrofolic acid from dihydrofolic acid by binding to and reversibly inhibiting the enzyme dihydrofolate reductase.
Following oral administration, Tilflotrim is well absorbed and widely distributed in the body. Peak concentrations are achieved in 2-4 hours. Therapeutic concentrations are maintained for 24-48 hours. Tilflotrim is eliminated in unchanged form in 48 hours following administration.

CONTRAINDICATIONS

Do not use in case of known hypersensitivity to the active substances, or to any of the excipients. If an allergic reaction occurs, the treatment should be withdrawn and antihistamine and symptomatic therapy should be undertaken as appropriate.
Do not use in animals suffering from impaired hepatic or renal function.
Do not use in pregnant animals.
Not authorised for use in birds producing eggs for human consumption.

ADVERSE REACTIONS

No undesirable effects are to be expected when the prescribed dosage regimen is followed.

DRUG INTERACTIONS

Concurrent administration of bacteriostatic antimicrobial agents (amphenicols, aminoglycosides, penicillins, tetracyclines), ionophore eimeriostatics, theophylline, non-steroidal anti-inflammatory agents, magnesium and calcium containing medications is not allowed.

WITHDRAWAL PERIODS

Pigs: Meat: 14 days.
Poultry: Meat: 12 days.
Eggs: Not authorised for use in birds producing eggs for human consumption.

SPECIAL WARNINGS

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

USER WARNINGS

People with known hypersensitivity to the active ingredients or excipients should avoid contact with the product. Avoid skin and ocular contact. Wear protective gloves and protective clothes when handling the veterinary medicinal product. In case of contact with skin or eyes, rinse abundantly with fresh water. If irritation persists and in case of incidental ingestion, seek immediately medical advice. Wash hands after use.

STORAGE CONDITIONS AND SHELF LIFE

Store in the original package between 5°C to 25°C, protected from light and moisture.
Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the container: 28 days.
Do not use this veterinary product after the expiry date which is stated on the label.
Keep out of the reach and sight of children.

MARKETING PACKAGING

The product is marketed in polymer bottles of 10, 20, 50, 100, 200, 250, 400, 450, 500 ml and 1, 2 litres.

MANUFACTURER

Belekotechnika Ltd, 9 Promyshlenny lane, 222823 Svisloch, Pukhovichi region, Minsk area, the Republic of Belarus.
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