Dopharma

Doxylin® 50% WSP

Doxycycline hyclate and citric acid





Characteristics

- Water soluble powder registered for the treatment of various respiratory diseases in calf, pig and chicken
- Contains citric acid to support solubility and stability
- Available in re-sealable plastic container of 1 or 5 kg

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Marketing authorisation holder
Dopharma Research B.V.

Packaging
Jar 1 kg
Bucket 5 kg

Pharmaceutical form
Powder for oral use

Composition
Per gram:
doxycycline 433 mg
equivalent to doxycycline hyclate 500 mg

Target species
Pre-ruminant calf, pig, chicken

Indications
Treatment of the following specified infections of the respiratory tract and the alimentary tract caused by micro-organisms susceptible to doxycycline.

Pre-ruminant calf:
- bronchopneumonia and pleuropneumonia caused by *Pasteurella* spp, *Streptococcus* spp, *Arcanobacterium pyogenes, Histophilus somni* and *Mycoplasma* spp.

Pig:
- atrophic rhinitis caused by *Pasteurella multocida* and *Bordetella bronchiseptica*;
- bronchopneumonia caused by *Pasteurella Multocida, Streptococcus suis* and *Mycoplasma hyorhinis*;
- pleuropneumonia caused by *Actinobacillus pleuropneumoniae*.

Chicken:
- infections of the respiratory tract caused by *Mycoplasma* spp, *Escherichia coli, Haemophilus paragallinarum* and *Bordetella avium*;
- Enteritis caused by *Clostridium perfrin gens* and *Clostridium colinum*.

Route of administration and dosage
Pre-ruminant calf:
Orally, in the drinking water or milk (replacer)
10 mg doxycycline hyclate per kg bodyweight (corresponding to 20 mg product per kg bodyweight), divided over 2 administrations, during 3 - 5 days.

Pig:
Orally, in the drinking water
10 mg doxycycline hyclate per kg bodyweight (corresponding to 20 mg product per kg bodyweight), during 3 - 5 days.

Poultry:
Orally, in the drinking water
25 mg doxycycline hyclate per kg bodyweight (corresponding to 50 mg product per kg bodyweight), during 3 - 5 days.

For the administration through the drinking water, the exact daily amount of product should be calculated, based on the recommended dose, and the number and weight of the animals to be treated, according to the following formula:

$$\frac{\text{mg product/kg bodyweight/day} \times \text{mean bodyweight (kg) of animals to be treated}}{\text{mean daily water consumption (litre) per animal}} = \ldots \text{ mg product per litre drinking water}$$

Withdrawal period
Pre-ruminant calf: meat and offal: 7 days
Pig: meat and offal: 8 days
Chicken: meat and offal: 5 days

Not permitted for use in laying birds producing eggs for human consumption.
Not permitted for use in cattle producing milk for human consumption.

Contraindications
- hypersensitivity to tetracyclines or to any of the excipients;
- administration to animals with severe liver or kidney insufficiency.

Adverse reactions
None known.

Special warnings
Special precautions for use in animals
Due to variability (time, geographical) in susceptibility of bacteria for doxycycline, bacteriological sampling and susceptibility testing of micro-organisms from diseased animals on farm are highly recommended. A high resistance rate of *E. coli*, isolated from chickens, against tetracyclines has been documented. Therefore the product should be used for the treatment of infections caused by *E. coli* only after susceptibility testing has been carried out. Resistance to tetracyclines has also been reported in pig respiratory pathogens (*A. pleuropneumoniae, S. suis*) and calf pathogens (*Pasteurella* spp) in some EU countries.
As eradication of the target pathogens may not be achieved, medication should therefore be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.

Use during pregnancy, lactation or lay
Due to deposit of doxycycline in young bone tissue, use of the product should be limited during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction
Do not use in conjunction with bactericidal antibiotics, such as penicillins and cephalosporins. Tetracyclines can chelate cations (e.g. Mg, Mn, Fe and Al) and this may lead to decreased bioavailability.

Overdose (symptoms, emergency procedures, antidotes)
In calves acute, sometimes fatal myocardial degeneration can occur following single or multiple dosages. Since mostly this is caused by overdosage, it is important to measure the dosage accurately.

Storage conditions and shelf life
Store below 25 ˚C.
Do not refrigerate or freeze.
Protect from frost.
Shelf life of the veterinary medicinal product as packaged for sale: 36 months (jar) or 18 months (bucket).
Shelf life after first opening of the immediate packaging: 3 months.
Shelf life after reconstitution in drinking water: 24 hours.
Shelf life after reconstitution in milk replacer: use immediately.

To be supplied only on veterinary prescription.
For the complete product information read the SPC.