

RONAXAN 20%w/w Powder for Oral Solution

Composition: Each Ronaxan 100g contains doxycycline (as hyclate) 20.0 g.

Product Description: Pale yellow powder

Pharmacodynamics: The tetracyclines are bacteriostatic antibiotics which inhibit the bacterial protein synthesis by blocking binding of transfer RNA to the messenger RNA-ribosome complex. Doxycycline is a second-generation tetracycline with a broad spectrum. The increased activity of doxycycline against numerous pathogens is attributed to a better penetration of the antibiotic into such pathogens. It is active against a wide range of gram-negative and gram-positive micro-organisms (*Pasteurella sp, Bordetella sp, Haemophilus sp, Escherichia coli, Salmonella sp, Clostridium sp*) as well as mycoplasma, including strains resistant to first generation tetracylines.

Pharmacokinetics: After oral administration in feed, doxycycline is highly bioavailable with mean serum concentrations of 0.54 µg/ml after administration of a 5 mg/kg dose twice a day during 5 days. The tissue concentrations are higher than the serum concentrations.

Indication: Pigs: Treatment of respiratory diseases caused by doxycycline-sensitive microorganism.

Routes of administration: Oral, in drinking water or liquid feed

Dosage:
Doxycycline: 10mg per kg and per day, i.e. 200 to 300 ppm of in the final feed. The treatment should be continued for 5 to 7 days.
Method of use in feed: RONAXAN 20% must first be diluted to produce a 1% premix containing 200g of doxycycline per 20kg of premix. 20 to 30kg of the 1% premix are then incorporated into 1000kg of the final feed so as to provide 200 to 300 ppm of active ingredient.
The medicated feed (or water) must be the only feed (or water) distributed throughout the duration of treatment.

Contraindications: None known

Warnings and Precautions:

Special precautions for use
None

Special warnings for the target species

- Use in the feed: the medicated feed must be the only feed distributed throughout the duration of the treatment
- Use in drinking water: the medicated drinking water must be the only water distributed throughout the duration of treatment

Special precautions to be taken by the person administering the product to animals

Wash hands after use. Keep out of the reach of children.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Drug containers and any residual contents should be disposed of safely according to the regulation in force.

Interactions with other medicaments: Doxycycline should not be associated with other antibiotics especially bactericidal drugs such as the beta-lactams. The half-life of doxycycline is reduced by concurrent administration of barbiturates or phenytoin. Simultaneous administration of oral absorbants and antiacids should be avoided as they reduce doxycycline availability.

Statement on usage during pregnancy and lactation: Tolerance studies in pregnant sows at three times the therapeutic dosage administered for eight days have shown doxycycline to be well tolerated without any signs of toxicity neither on sows nor on piglets, irrespective of the stage of pregnancy.

Adverse Effects: None known

Overdose and Treatment: RONAXAN 20% is well tolerated as shown in the tolerance studies when administered to 45 days old piglets, at five times the therapeutic dosage and twice as long as recommended.

Storage Conditions: The product should be stored at a temperature not exceeding 25°C, protected from light.

Withdrawal Period:

Pigs: 6 days after the end of treatment

Packing: 100 g and 1 kg in polyethylene box

FOR VETERINARY USE ONLY

Manufactured by :



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Registration holder and repacker:



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5LRONAX3-100 03/XX

W10cm H14cm

LABEL CODE:		VERSION	COLORS
5LRONAX3-100			Black
PRODUCT: RONAXAN 20%		Version: 3	! Please use the official PANTONE® (P) matching system for an accurate color representation.
PACK SIZE: 100 G		MMM/YY: XXX	
COUNTRY: MY			
DIMENSIONS: cm = 10 x 14			
Marketing approval:		Regulatory approval:	GMP approval:
COMPLETE NAME:		COMPLETE NAME:	COMPLETE NAME:
DATE + SIGNATURE:		DATE + SIGNATURE:	DATE + SIGNATURE: