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Ronaxan 20mg, 100mg Tablet

Species:	Cats, Dogs
Therapeutic indication:	**Pharmaceuticals: Antimicrobials: Oral preparations:** Tablets
Active ingredient:	Doxycycline
Product:	Ronaxan Tablets
Product index:	Ronaxan Tablets

Qualitative and quantitative composition

Each tablet contains:

Active substances: Doxycycline 20 mg or 100 mg as doxycycline hyclate.

For the full list of excipients, see below.

Pharmaceutical form

Round, biconvex, light yellow to yellow scored tablet. The tablets can be divided into equal parts.

Clinical particulars

Target species

20 mg tablets are indicated for use in both cats and dogs, 100 mg tablets are indicated for use in dogs only.

Indications for use

Treatment of respiratory tract infections in cats and dogs, including rhinitis, tonsillitis, bronchopneumonia and feline respiratory disease, due to organisms sensitive to doxycycline including: *Pasteurella* spp., *Bordetella bronchiseptica*, *Staphylococcus aureus* and other *Staphylococcus* spp., and *Streptococcus* spp.

Treatment of arthropod-borne *Ehrlichia canis* infection in cats and dogs.

Contra-indications

Do not use in pregnant animals. Do not use in known cases of hypersensitivity to the active ingredient. Vomiting, oesophagitis and oesophageal ulcerations have been reported as side effects

following doxycycline therapy, and Ronaxan should not therefore be administered to patients with dysphagia or diseases accompanied by vomiting.

Special warnings for each target species

None known.

Special precautions for use in animals

Do not exceed the recommended dosage. Tablets should be administered at feeding time.

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

Wash hands thoroughly after use. Handle the tablets with care if you know you are hypersensitive (allergic) to tetracycline. In case of accidental ingestion, seek medical advice.

Adverse reactions

Photodermatitis has occurred following tetracycline therapy after exposure to intense sunlight or ultraviolet light. Use of tetracycline during the period of tooth development may lead to tooth discolouration. Doxycycline, because of its lower affinity for calcium, carries a lower risk than other tetracyclines. Refer also to section '*Contra-indications*'.

Use during pregnancy, lactation or lay

Laboratory studies have not revealed any teratogenic, or embryotoxic effect of doxycycline in the rat and rabbit. However, as there is no information available in the target species, use is not recommended during pregnancy.

Interactions

Cross resistance to other tetracyclines can occur. Doxycycline should not be used concurrently with other antibiotics especially bactericidal drugs such as the β-lactams. The half-life of doxycycline is reduced by concurrent administration of barbiturates or phenytoin. Simultaneous administration of oral absorbents, iron preparations and antacids should be avoided as they reduce doxycycline availability.

Amounts to be administered and administration route

The tablets are for oral administration. The dosage is 10 mg doxycycline per kilogram of bodyweight (one 20 mg tablet per 2 kg or one 100 mg tablet per 10 kg of bodyweight), administered daily for up to five days. In order to adjust the dosage, the tablets can be divided into two equal parts.

For treatment of infections caused by *Ehrlichia canis* the dose is 10 mg/kg/day for 28 days. Complete eradication of the pathogen is not always achieved but extended treatment for 28 days leads to a resolution of the clinical signs and a reduction of the bacterial load. Longer duration of treatment, based on a benefit-risk assessment by the responsible veterinarian, may be required in

severe and chronic ehrlichiosis. All treated patients should be regularly monitored even after clinical cure.

Tablets should be administered at feeding time.

Overdose

The toxicity and tolerance studies have shown that this product is very well tolerated in cats after five times the recommended dose. Raised levels of SGPT, GGT, SAP and total bilirubin were noted in dogs which received three or five times the recommended dose. Some vomiting can occur in dogs with five times the recommended dosage.

Pharmacological particulars

Doxycycline is a second generation, broad spectrum cycline belonging to the tetracycline family.
ATCvet code: QJ01AA02

Pharmacodynamic properties

It is active against a large number of Gram positive and Gram negative pathogens including strains resistant to first generation tetracyclines. It is essentially bacteriostatic; it inhibits the bacterial protein synthesis by blocking binding of transfer RNA to the messenger RNA-ribosome complex.

Pharmacokinetic properties

After oral administration in dogs and cats at the recommended dose of 10 mg/kg, doxycycline is rapidly absorbed reaching the maximal plasma concentration in about 3 hours (Tmax). The peak concentration (Cmax) is 4.5 µg/ml and 3.8 µg/ml in dogs and cats respectively. The oral bioavailability of doxycycline after repeated administration is approximately 45% in both species, and is not affected by the presence of food. In spite of a high protein binding rate, the volume of distribution of doxycycline is high demonstrating that doxycycline is broadly distributed in organs and tissues. Doxycycline is mainly excreted as unchanged drug and eliminated in faeces and urine. Mean elimination half-life is 7.8 hours in dogs and 5.8 hours in cats

Pharmaceutical particulars

Excipients

Magnesium Stearate, Microcrystalline Cellulose.

Major incompatibilities

None known.

Shelf life

Shelf life of the product as packaged for sale: 2 years.

Special precautions for storage

Do not store above 25 °C. Store in a dry place. Protect from light.

Immediate packaging

Packs of 5 blister strips each containing 10 tablets.

Disposal

Any unused product or waste materials derived from such products should be disposed of in accordance with local requirements.

Marketing Authorisation Number

Vm 08327/4068

Vm 08327/4069

Significant changes

Legal category

Legal category:	POM-V

GTIN

GTIN description:	Ronaxan Tablets 20 mg
GTIN:	03661103044162
GTIN description:	Ronaxan Tablets 100 mg
GTIN:	03661103044161