

Respicure 50 mg Tablet

Doxycycline 50mg tablets

COMPOSITION

Each tablet contains:

Doxycycline.....50 mg

DESCRIPTION

The finished product is a dark blue, oval shaped, scored, coated tablet.

PHARMACODYNAMICS

Doxycycline is a second-generation tetracycline. The product is mainly bacteriostatic; it inhibits bacterial protein synthesis by blocking the binding of transfer RNA at the messenger RNA-ribosome-complex. Doxycycline has a time-dependent concentration-enhanced effect with AUC/MIC being the main pharmacodynamic index.

Resistance is mainly mediated by efflux pumps or ribosomal protection proteins. Cross-resistance among tetracyclines is common but depends on resistance mechanisms: i.e. mutation in efflux pumps that renders resistance to tetracycline may still be sensitive to doxycycline. However, induction of the ribosomal protection proteins confers cross-resistance to doxycycline.

PHARMACOKINETICS

After oral administration doxycycline is mainly absorbed from the duodenum and jejunum. Following oral administration, the bioavailability is > 50%. Doxycycline is widely distributed throughout the body, and can accumulate intracellularly for example in leukocytes. It is deposited in active bone tissue and teeth. Doxycycline is primarily eliminated through faeces by direct intestinal excretion and to a lesser extent by glomerular excretion and biliary secretion.

INDICATIONS

Treatment of the following conditions caused by bacteria sensitive to doxycycline:

Dogs:

Rhinitis caused by *Bordetella bronchiseptica* and *Pasteurella* spp.; Bronchopneumonia caused by *Bordetella* spp. and *Pasteurella* spp.; Interstitial nephritis caused by *Leptospira* spp.

Cats:

Respiratory infections caused by *Bordetella bronchiseptica*, *Chlamydomphila felis* and *Pasteurella* spp.

TARGET SPECIES: Dogs and cats.

ROUTE OF ADMINISTRATION

By the oral route

RECOMMENDED DOSE/USE INSTRUCTION

The recommended dose for dogs and cats is 10 mg doxycycline per kg bodyweight per day (one tablet per 5 kg body weight). The majority of routine cases are expected to respond after between 5 and 7 days of therapy. Therapy should continue for 2 to 3 days beyond the clinical cure for acute infections. In chronic or refractory cases, a longer course of therapy, up to 14 days, may be required. In dogs with interstitial nephritis due to leptospirosis, treatment for 14 days is recommended. In cats with *C. felis* infections, it is recommended to administer treatment for a minimum period of 28 days in order to ensure elimination of the organism. To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. Tablets should be administered together with the food.

The following table is intended as a guide to dispensing the product at the standard dose rate of 10 mg per kg bodyweight per day.

Body weight	Dose (mg)	Respicure 50 mg
0.75 kg – 1.25 kg	12.5	½ Tablet
>1.25 kg – 2.5 kg	25	½ Tablet
>2.5 kg – 3.75 kg	37.5	½ Tablet
>3.75 kg – 5 kg	50	1 Tablet
>5 kg – 6.25 kg	62.5	1 Tablet and ½ Tablet
>6.25 kg – 7.5 kg	75	1 Tablet and ½ Tablet
>7.5 kg – 10 kg	100	2 Tablets
>10 kg – 12.5 kg	125	2 Tablets and ½ Tablet
>12.5 kg – 15 kg	150	3 Tablets
>15 kg – 20 kg	200	4 Tablets
>20 kg – 25 kg	250	5 Tablets
>25 kg – 30 kg	300	6 Tablets
>30 kg – 35 kg	350	7 Tablets
>35 kg – 40 kg	400	8 Tablets

CONTRAINDICATIONS

Do not use in cases of hypersensitivity to tetracyclines or to any of the excipients.

WARNINGS AND PRECAUTIONS

Special warnings for each target species

None.

Special precautions for use

Special precautions for use in animals

The product should be administered with caution to animals with dysphagia or diseases accompanied with vomiting, since administration of doxycycline hyclate tablets has been associated with oesophageal erosion.

In order to reduce the likelihood of oesophageal irritation as well as other gastrointestinal side effects, the product should be administered together with food. Special care should be taken when administering the product to animals with liver disease, since increases in hepatic enzymes have been documented in some animals after doxycycline treatment.

The product should be administered with caution to young animals, since tetracyclines as a class may cause permanent discolouration of the teeth, when administered during tooth development. However, human literature indicates that doxycycline is less likely than other tetracyclines to cause these abnormalities, due to its reduced ability to chelate calcium.

Due to the likely variability (time, geographical) in the occurrence of resistance of bacteria for doxycycline, bacteriological sampling and susceptibility testing are recommended. Official, national and regional antimicrobial policies should be taken into account when the product is used. Use of the product deviating from the instructions may increase the prevalence of bacteria resistant to doxycycline and may decrease the effectiveness of treatment with other tetracyclines, due to the potential for cross-resistance.

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

Tetracyclines may cause hypersensitivity (allergy) reactions.

People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.

Wash hands after use.

If you develop symptoms following exposure such as skin rash, seek medical advice immediately and show the package leaflet to the physician.

Doxycycline may cause gastrointestinal disturbances after accidental ingestion, especially by children. To avoid accidental ingestion, particularly by a child, unused tablet parts should be returned to the open blister space and inserted back into the carton. In case of accidental ingestion, particularly by children, seek medical advice.

- Keep out of reach of children

- Jauhkan daripada kanak-kanak

INTERACTIONS WITH OTHER MEDICAMENTS

Do not administer concurrently with bactericidal antibiotics such as penicillins and cephalosporins. Oral absorbents and substances containing multivalent cations such as antacids and iron salts should not be used from 3 hours before to 3 hours after

the administration of doxycycline. The half-life of doxycycline is reduced by concurrent administration of antiepileptic drugs such as phenobarbital and phenytoin.

PREGNANCY AND LACTATION

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Tetracyclines as a class can retard foetal skeletal development (fully reversible) and cause discolouration of the deciduous teeth. However, evidence from human literature suggests that doxycycline is less likely to cause these abnormalities than other tetracyclines. Use only according to the benefit/risk assessment by the responsible veterinarian.

SIDE EFFECTS/ADVERSE REACTIONS

Gastrointestinal disorders such as vomiting, diarrhoea and oesophagitis have been reported as side effects following doxycycline therapy.

In very young animals discoloration of the teeth may occur by the formation of a tetracycline-calcium phosphate complex.

Hypersensitivity reactions, photosensitivity and in exceptional cases photodermatitis may occur after exposure to intense daylight.

Retardation of skeletal growth of young animals (reversible upon discontinuation of therapy) is known to occur with use of other tetracyclines and might occur following administration of doxycycline.

SIGNS AND SYMPTOMS OF OVERDOSE AND TREATMENT

In cases of overdose no symptoms are to be expected other than those mentioned in section adverse reaction.

STORAGE CONDITIONS

Store in a dry place, below 30°C. Protect from light.

MAXIMUM RESIDUAL LIMIT

Not applicable.

SHELF LIFE: 3 years

SHELF LIFE AFTER OPENING: 24 hours

WITHDRAWAL PERIOD: Not applicable.

PACKAGING: Each box contains 100 tablets in 10 blister strips.

REVISED DATE: Jun 11, 2020

 **Vemedim**
Animal Health

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