1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ronaxan 20 mg tablets for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Doxycycline 20 mg (as doxycycline hyclate 23.08 mg)

Excipients:

Qualitative composition of excipients and other constituents
Microcrystalline cellulose
Magnesium stearate

Round, biconvex light yellow/yellow to beige scored tablets that could appear mottled.
The tablets can be divided into two equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats

3.2 Indications for use for each target species

Dogs:
For the treatment of respiratory tract infections including rhinitis, tonsillitis and bronchopneumonia caused by *Bordetella bronchiseptica* and *Pasteurella* spp. susceptible to doxycycline.

For the treatment of canine ehrlichiosis caused by *Ehrlichia canis*.

Cats:
For the treatment of respiratory tract infections including rhinitis, tonsillitis and bronchopneumonia caused by *Bordetella bronchiseptica* and *Pasteurella* spp. susceptible to doxycycline.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with renal or hepatic insufficiency.
Do not use in animals with diseases associated with vomiting or dysphagia.
Do not use in animals with known photosensitivity.
Do not use in puppies and kittens before completion of teeth enamel formation.

3.4 Special warnings

Ehrlichia canis infection: treatment should be initiated at the onset of clinical signs. Complete eradication of the pathogen is not always achieved, but treatment for 28 days generally leads to a resolution of the clinical signs and a reduction of the bacterial load. A longer duration of treatment, based on a benefit/risk assessment by the responsible veterinarian, may be required particularly in severe or chronic ehrlichiosis. All treated animals should be regularly monitored, even after clinical cure.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Tablets should be administered with food to avoid vomiting and to reduce the likelihood of oesophageal irritation.

The veterinary medicinal 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.

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.

Use of the veterinary medicinal product deviating from the instructions given in the summary of product characteristics (SPC) 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.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to doxycycline or other tetracyclines should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
In case of skin irritation, seek medical advice immediately and show the package leaflet or the label to the physician.
Accidental ingestion, especially by children, may cause adverse events such as emesis. To avoid accidental ingestion, blisters should be inserted back into the outer packaging and kept in a safe place.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare (1 animal / 10 000 animals treated, including isolated reports):	Gastroinestinal disorders (e.g. vomiting, diarrhoea, hypersalivation, nausea and oesophagitis) Photosensitization (and photodermatitis)[1] Dental discolouration[2]

[1] After exposure to intense sunlight or ultraviolet light.
[2] If used during the period of tooth development.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or embryotoxic effects of doxycycline. However, as there is no information available in the target species, the use is not recommended during pregnancy.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Doxycycline should not be used concurrently with other antibiotics, especially bactericidal drugs such as the β-lactams. Cross-resistance to tetracyclines may occur.
The half-life of doxycycline is reduced by concurrent administration of barbiturates, phenytoin and carbamazepine.
Dosage adjustments may be necessary in subjects under anticoagulant therapy, as tetracyclines depress the plasma activity of prothrombin.
Simultaneous administration of oral absorbents, antacids and preparations including multivalent cations should be avoided as they reduce doxycycline availability.

3.9 Administration route and dosage

Oral use.

The dosage is 10 mg doxycycline per kg bodyweight per day corresponding to one tablet per 2 kg bodyweight. To ensure a correct dosage, body weight should be determined as accurately as possible to avoid overdosing or underdosing. To adjust the dosage, the tablets can be divided into two equal parts. The dosage can be divided into two daily administrations. The duration of treatment might be adapted depending on the clinical response, after benefit/risk assessment by the veterinarian.

Disease	Dosage regimen	Duration of treatment
Respiratory tract infection	10 mg/kg per day	5-10 days
Canine ehrlichiosis	10 mg/kg per day	28 days

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Vomiting may occur in dogs with 5 times the recommended dose. Increased levels of ALT, GGT, ALP and total bilirubin were reported in dogs at 5-fold overdose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01AA02.

4.2 Pharmacodynamics

Doxycycline is a broad-spectrum tetracycline-class antibiotic active against a large number of gram positive and gram negative bacteria including both aerobic and anaerobic species.

Doxycycline inhibits bacterial protein synthesis by binding to the 30-S ribosomal subunits. This interferes with binding of aminoacetyl-tRNA to the acceptor site on the mRNA ribosome complex and prevents coupling of amino acids to the elongating peptide chains; doxycycline has a predominantly bacteriostatic activity.

The penetration of doxycycline into the bacterial cell takes place by both active transport and passive diffusion.
The main mechanisms of acquired resistance to tetracycline class antibiotics include active efflux and ribosomal protection. A third mechanism is enzymatic degradation. The genes mediating resistance may be carried on plasmids or transposons, as for example, *tet*(M), *tet*(O), and *tet*(B) that can be found in both gram-positive and gram-negative organisms including clinical isolates.

Cross-resistance to other tetracyclines is common but depends on the mechanism conferring resistance. Due to the greater liposolubility and greater ability to pass through cell membranes (in comparison to tetracycline), doxycycline retains a certain degree of efficacy against microorganisms with acquired resistance to tetracyclines via efflux pumps. However, resistance mediated by ribosomal protection proteins confer cross-resistance to doxycycline.

The following MIC values for the targeted bacteria were collected between 2017 and 2018 as a part of ongoing European surveillance studies:

Bacterial pathogen	**Origin (*number of strains tested*)**	**MIC_{50} (mcg/ml)**	**MIC_{90} (mcg/ml)**
Bordetella bronchiseptica	Dog – respiratory tract (*38*)	0.12	0.5
Bordetella bronchiseptica	Cat – respiratory tract (*11*)	0.12	0.12
Pasteurella spp.	Dog – respiratory tract (*27*)	0.12	0.25
Pasteurella spp.	Cat– respiratory tract (*77*)	0.12	0.25

Antibiotic susceptibility data for *Ehrlichia canis* are limited.

4.3 Pharmacokinetics

Absorption:
After oral administration, the bioavailability of doxycycline is 45% in dogs and 48% in cats. Peak concentrations of 4.5 mcg/ml (dogs) and 3.8 mcg/ml (cats) are reached within 3 hours after oral administration, supporting that doxycycline is rapidly absorbed from the gastro-intestinal tract.

Distribution:
Doxycycline is broadly distributed throughout the organism due to its physicochemical characteristics, as it is highly liposoluble. The distribution volume is 1.72 l/kg in dogs and 0.9 l/kg in cats, supporting that doxycycline diffuses from blood into tissues. Protein binding in dogs is reported as 91.75 % ± 0.63 and 91.4% in the literature. In cats a publication reports a protein binding of 98.35% (+/-0.24). The tissue concentrations, with the exception of the skin, are generally higher than the plasma levels, including the excretion organs (liver, kidney and intestines) and for the lungs.

Elimination:
After a single administration, the half-life elimination ($T_{1/2}$) is 7.84 hours and 5.82 hours, in dogs and cats respectively. Excretion occurs in an unchanged active form (90%) via the faeces (approximately 75%), via the urine (approximately 25%) and less than 5% via the bile ducts.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Do not store above 25°C.
Keep the blister in the outer carton.

5.4 Nature and composition of immediate packaging

Blisters (polyvinyl chloride acetyl chloride complex and aluminium foil) of 10 tablets packed in a cardboard box.

Cardboard box containing 1 blister of 10 tablets.
Cardboard box containing 2 blisters of 10 tablets.
Cardboard box containing 5 blisters of 10 tablets.
Cardboard box containing 10 blisters of 10 tablets.
Cardboard box containing 50 blisters of 10 tablets.
Cardboard box containing 100 blisters of 10 tablets.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/075/001

8. DATE OF FIRST AUTHORISATION

12/10/1995

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10/10/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).