SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RONAXAN 20mg Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance :

Doxycycline (as doxycycline hyclate)	20 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Cats and dogs

4.2 Indications for use specifying the target species

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.

4.3 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.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

i) Special precautions for use in animals

Do not exceed the recommended dosage.

Tablets should be administered at feeding time.

ii) Special precautions to be taken by the person administering the medicinal product to the 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.

4.6 Adverse reactions (frequency and seriousness)

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 4.3.

4.7 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.

4.8 Interaction with other medicinal products and other forms of interaction

Cross resistance to other tetracyclines can occur.

Doxycycline should not be used concurrently with other antibiotics especially bactericidal drugs such as the ß-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.

4.9 Amounts to be administered and administration route

The tablets are for oral administration. The dosage is 10 mg doxycycline per kilogram of bodyweight (one tablet per 2 kg 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Summary presentation of the active ingredient

Doxycycline is a second generation, broad spectrum cycline belonging to the tetracycline family.

ATC Vet Code:

QJ01AA02

5.1 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.

5.2 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 4.5µg/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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate
Microcrystalline Cellulose

6.2 Major incompatibilities

None known.

6.3 Shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time

Two years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Thermoformed blister packs that consist of an opaque white sheet of a poly vinyl chloride acetyl chloride complex (sheet 250 microns in thickness) and aluminium foil 20 microns in thickness. Each blister contains 10 tablets.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate.

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4069

9. DATE OF THE FIRST AUTHORISATION

27 June 1991

10. DATE OF REVISION OF THE TEXT

November 2018

ANY OTHER INFORMATION REQUIRED BY THE SECRETARY OF STATE

Not applicable.

Approved 01 November 2018