PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard for 1 x 10 tablets, 1 x 50 tablets, 2 x 10 tablets, 5 x 10 tablets, 10 x 10 tablets, 50 x 10 tablets and 100 x 10 tablets}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ronaxan 100 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Doxycycline 100 mg (as doxycycline hyclate 115.4 mg)

3. PACKAGE SIZE

1 x 10 tablets
1 x 50 tablets
2 x 10 tablets
5 x 10 tablets
10 x 10 tablets
50 x 10 tablets
100 x 10 tablets

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 61700/5023
Vm 61700/3034

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {Blister of 10 or 50 tablets}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ronaxan 100 mg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Doxycycline hyclate

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Ronaxan 100 mg Tablets for Dogs and Cats

2. Composition

Each tablet contains:

Active substance:
Doxycycline 100 mg (as doxycycline hyclate 115.4 mg)

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

3. Target species

Dogs and cats.

4. Indications for use

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 (a disease transmitted by ticks) 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.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or 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 (difficulty to swallow).
Do not use in animals with known photosensitivity.
Do not use in puppies and kittens before completion of teeth enamel formation.

6. Special warnings

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.

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 leaflet 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.

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or embryotoxic effects (malformations or deformities of the embryo) 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.

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 (for example penicillin, ampicillin). Cross-resistance to tetracyclines may occur.
The half-life of doxycycline is reduced by concurrent administration of barbiturates (some types of sedatives or tranquilisers), phenytoin and carbamazepine (two types of anti-epileptic medications).
Dosage adjustments may be necessary in subjects under anticoagulant therapy (blood thinners), as tetracyclines depress the plasma activity of prothrombin.
Simultaneous administration of oral absorbents, antacids (protectants for the stomach) and preparations including multivalent cations should be avoided as they reduce doxycycline availability.

Overdose:
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.

7. Adverse events

Dogs and cats:

Very rare (1 / 10 000 animals treated, including isolated reports):
Gastrointestinal disorders (e.g. vomiting, diarrhoea, hypersalivation, nausea and oesophagitis (inflammation of the oesophagus))
Photosensitization (and photodermatitis (abnormal skin reaction to light)[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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use.

The dosage is 10 mg doxycycline per kg bodyweight per day corresponding to one tablet per 10 kg bodyweight. 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

9. Advice on correct administration

To ensure a correct dosage, bodyweight 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. Tablets should be administered with food to avoid vomiting.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25°C.
Keep the blister in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 61700/5023
Vm 61700/3034

Cardboard box of either 1, 2, 5, 10, 50 or 100 blisters of 10 tablets.
Cardboard box of 1 blister of 50 tablets.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany
+353 1 291 3985

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet
31000 Toulouse
France

17. Other information

POM-V

Gavin Hall
Approved: 02 December 2025