# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrobactin 500 mg tablets for dogs and cats

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains:

**Active substance:**
Metronidazole 500 mg

**Excipients:**
For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Tablet.
Light brown with brown spots, round and convex flavoured tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 equal parts.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs and cats.

### 4.2 Indications for use, specifying the target species

Treatment of gastrointestinal tract infections caused by *Giardia* spp. and *Clostridium* spp. (i.e. *C. perfringens* or *C. difficile*).
Treatment of infections of the urogenital tract, oral cavity, throat and skin caused by obligate anaerobic bacteria (e.g. *Clostridium* spp.) susceptible to metronidazole.

### 4.3 Contraindications

Do not use in case of hepatic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

### 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

Special precautions for use in animals
Due to the likely variability (time, geographical) in the occurrence of metronidazole resistant bacteria, bacteriological sampling and susceptibility testing are recommended.
Whenever possible, the product should only be used based on susceptibility testing.
Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.
Especially after prolonged treatment with metronidazole neurological signs could occur.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Metronidazole has confirmed mutagenic and genotoxic properties in laboratory animals as well as in humans. Metronidazole is a confirmed carcinogen in laboratory animals and has possible carcinogenic effects in humans. However, there is inadequate evidence in humans for the carcinogenicity of metronidazole.
Metronidazole may be harmful for the unborn child.
Avoid contact with the skin or mucous membranes including hand-to-mouth contact. To avoid such contact wear impervious gloves when handling the product and/or for direct administration into the animal's mouth.
Do not allow treated dogs to lick persons immediately after intake of the medication.
In case of skin contact, wash thoroughly the affected area.
To avoid accidental ingestion, particularly by a child, unused parts of the tablets should be returned to the open blister space, inserted back into the outer packaging and kept in a safe place out of the sight and reach of children. The remaining part should be used at the time of next administration.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands thoroughly after use.
Metronidazole may cause hypersensitivity reactions. People with known hypersensitivity to metronidazole should avoid contact with the veterinary medicinal product.

## 4.6 Adverse reactions (frequency and seriousness)

The following adverse reactions may occur after administration of metronidazole: vomiting, hepatotoxicity and neutropenia. In very rare cases neurological signs may occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

## 4.7 Use during pregnancy and lactation

Studies in laboratory animals have shown inconsistent results with regard to teratogenic/embryotoxic effects of metronidazole. Therefore, use of this product during pregnancy is not recommended. Metronidazole is excreted in milk and use during lactation is therefore not recommended.

## 4.8 Interaction with other medicinal products and other forms of interaction

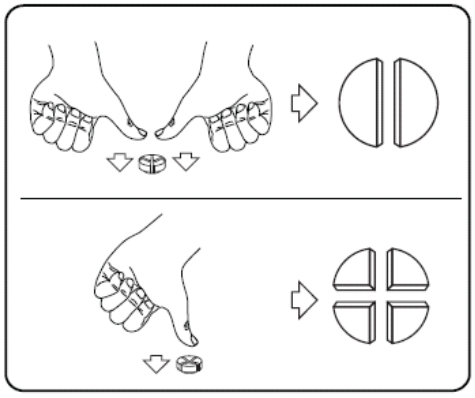
Metronidazole may have an inhibitory effect on the degradation of other drugs in the liver, such as phenytoin, cyclosporine and warfarin.
Cimetidine may decrease the hepatic metabolism of metronidazole resulting in increased serum concentration of metronidazole.
Phenobarbital may increase hepatic metabolism of metronidazole resulting in decreased serum concentration of metronidazole.

## 4.9 Amounts to be administered and administration route

For oral use.
The recommended dose is 50 mg metronidazole per kg bodyweight per day, for 5-7 days. The daily dose may be divided equally for twice daily administration (i.e. 25 mg/kg bodyweight twice daily).

To ensure administration of the correct dosage bodyweight should be determined as accurately as possible.

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



Halves: press down with your thumbs on both sides of the tablet.
Quarters: press down with your thumb in the middle of the tablet.

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

Adverse events are more likely to occur at doses and treatment durations in excess of the recommended treatment regimen. If neurological signs occur, treatment should be discontinued and the patient should be treated symptomatically.

### 4.11 Withdrawal period(s)

Not applicable

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiprotozoals, agents against protozoal diseases, nitroimidazole derivatives.
ATC vet code: QP51AA01.

### 5.1 Pharmacodynamic properties

After metronidazole has penetrated the bacteria the molecule is reduced by the sensitive bacteria (anaerobe). The metabolites that are created have a toxic effect on the bacteria through binding to the bacterial DNA. In general metronidazole is bactericidal for sensitive bacteria in concentrations equal to or a little higher than the minimum inhibiting concentration (MIC).
Clinically metronidazole does not have any relevant effect on facultative anaerobe, obligate aerobe and microaerophilic bacteria.

### 5.2 Pharmacokinetic particulars

Metronidazole is immediately and well absorbed after oral administration. After 1 hour a plasma concentration of 10 micrograms/ml was reached with a single dose of 50 mg. The bioavailability of metronidazole is almost 100% and the half life in the plasma is approximately 8-10 hours. Metronidazole penetrates well into the tissues and bodily fluids, such as saliva, milk, vaginal secretions and semen. Metronidazole is primarily metabolised in the liver. Within 24 hours after oral administration 35-65% of the administered dose (metronidazole and the metabolites thereof) is excreted in the urine.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Cellulose, microcrystalline
Sodium starch glycolate, type A
Hydroxypropylcellulose
Yeast (dried)
Chicken Flavour
Magnesium stearate

### 6.2 Major incompatibilities

Not applicable.

### 6.3 Shelf life

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

Shelf life of divided tablets: 3 days.

### 6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

### 6.5 Nature and composition of immediate packaging

Aluminium - PVC/PE/PVDC blister
Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 25 or 50 blisters of 10 tablets
Cardboard box containing 10 boxes, each containing 1 or 10 blisters of 10 tablets

Not all pack sizes may be marketed.

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

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

## 7. MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

## 8. MARKETING AUTHORISATION NUMBER

Vm 50406/4017

## 9. DATE OF FIRST AUTHORISATION

18 December 2015

## 10. DATE OF REVISION OF THE TEXT

April 2022

Approved 07 April 2022