

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Metrobactin 500 mg tablets for dogs and cats (AT, BE, BG, CY, CZ, DE, EL, ES, FR, HR, HU, IE, IT, LU, NL, PT, RO, SI, SK, UK)

Metrobactin vet 500 mg tablets for dogs and cats (DK, FI, IS, NO, SE, EE, LT, LV, PL)

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

1 tablet contains:

#### **Active substance:**

Metronidazole            500 mg

#### **Excipient(s):**

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 *Clostridia* 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. *Clostridia* 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**

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.

In very rare cases, neurological signs may occur especially after prolonged treatment with metronidazole.

##### **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. Impervious gloves should be worn during administration of the product to avoid skin contact with the product.

To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the carton.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands thoroughly after handling the tablets.

#### **4.6 Adverse reactions (frequency and seriousness)**

The following adverse reactions may occur after administration of metronidazole: vomiting, hepatotoxicity, neutropenia and neurologic signs.

#### **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 administration.

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).

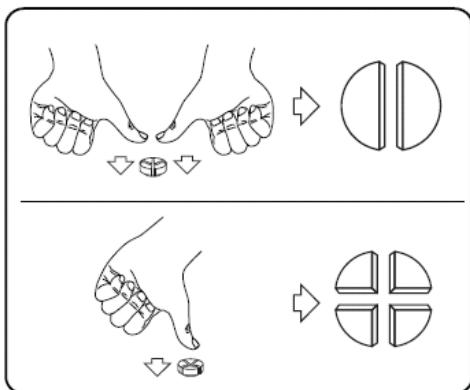
To ensure administration of the correct dosage bodyweight should be determined as accurately as possible.

The following table is intended as a guide to dispensing the product at the recommended dose rate of 50 mg per kg bodyweight per day.

Bodyweight	Metrobactin 250 mg for dogs and cats		Metrobactin 500 mg for dogs and cats
1 kg – 1.25 kg	◻		
>1.25 kg – 2.5 kg	◐		
>2.5 kg – 3.75 kg	◑		
>3.75 kg – 5 kg	⊕	or	◐
>5 kg – 7.5 kg	⊕ ◐	or	◑
>7.5 kg – 10 kg	⊕ ⊕	or	⊕
>10 kg – 15 kg	⊕ ⊕ ⊕	or	⊕ ◐
>15 kg – 20 kg	⊕ ⊕ ⊕ ⊕	or	⊕ ⊕
>20 kg – 25 kg			⊕ ⊕ ◐
>25 kg – 30 kg			⊕ ⊕ ⊕
>30 kg – 35 kg			⊕ ⊕ ⊕ ◐
>35 kg – 40 kg			⊕ ⊕ ⊕ ⊕

◻ = ¼ Tablet    ◐ = ½ Tablet    ◑ = ¾ Tablet    ⊕ = 1 Tablet

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)**

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:** (nitro) imidazole derivatives  
**ATC code:** QP51AA01, QJ01X D01

#### **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 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**

Le Vet Beheer B.V.  
Wilgenweg 7  
3421 TV Oudewater  
The Netherlands

## **8. MARKETING AUTHORISATION NUMBER**

Vm 41821/4030

## **9. DATE OF FIRST AUTHORISATION**

18 December 2015

**10. DATE OF REVISION OF THE TEXT**

December 2015

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 18 December 2015