Metrobactin®

500 mg tablets for dogs and cats

UK IE

Marketing authorisation holder: Le Vet Beheer BV, Wilgenweg 7, 3421 TV Oudewater, The Netherlands

Manufacturer responsible for batch release: LelyPharma BV, Zuiveringweg 42, 4283 PZ Lelystad, The Netherlands

Name of the veterinary medicinal product: Metrobactin 500 mg tablets for dogs and cats. Metronidazole.

Statement of the active substance and other ingredients:

1 tablet contains:
Active substance: Metronidazole 500 mg
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.

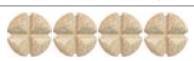
Indications: Treatment of gastrointestinal tract infections caused by *Giardia* spp. and *Clostridia* spp. (i.e. *C. perfringens* or *C. difficile*).
Treatment of infections of the urogenital tract, oral cavity, throat and skin caused by obligate anaerobic bacteria (e.g. *Clostridia* spp.) susceptible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

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.

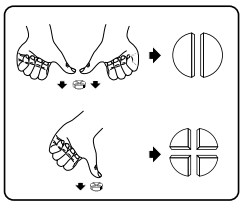
Adverse reactions: The following adverse reactions may occur after administration of metronidazole: vomiting, hepatotoxicity, neutropenia and neurologic signs. I
f you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinarian.

Target species: Dogs and cats.

Dosage for each species, route and method of administration:
For oral administration.The recommended dose is 50 mg metronidazole per kg body weight per day for 5-7 days.
The daily dose may be divided equally for twice daily administration (i.e. 25 mg/kg body weight twice daily).
To ensure administration of the correct dosage, body weight 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 body weight per day.

Body weight (kg)	Metrobactin 250 mg for dogs and cats		Metrobactin 500 mg for dogs and cats
1 – 1.25			
>1.25 – 2.5			
>2.5 – 3.75			
>3.75 – 5		or	
>5 – 7.5		or	
>7.5 – 10		or	
>10 – 15		or	
>15 - 20		or	
>20 – 25			
>25 – 30			
>30 - 35			
>35 – 40			

= ¼ tablet	= ½ tablet	= ¾ tablet	= 1 tablet
			



Advice on correct administration: Tablets can be divided into equal halves or quarters 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.
Equal halves: Press down with your thumbs on both sides of the tablet.
Equal quarters: Press down with your thumb in the middle of the tablet.

Withdrawal period: Not applicable.

Special storage precautions:
Keep out of the sight and reach of children. Shelf life of divided tablets: 3 days.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

Special warnings:
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.
User warnings: 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 labelling to the physician.
Wash hands thoroughly after handling the tablets.
Use during pregnancy or 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.
Interactions 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.
Overdose (symptoms, emergency procedures, antidotes):
Adverse events are more likely to occur at doses and treatment duration in excess of the recommended treatment regimen.
If neurological signs occur, treatment should be discontinued and the patient should be treated symptomatically.

Special precautions for the disposal of unused product or waste materials: Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Date on which the package leaflet was last approved: 23-09-2015

Other information: For animal treatment only. To be supplied only on veterinary prescription.

UK: Vm 41821/4030 POM-V Prescription Only Medicine - Veterinarian

IE: VPA 10475/022/002 POM Prescription Only Medicine

Veterinary medicinal product authorised for use in UK and IE.
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.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Dechra Veterinary Products Limited,
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Hadnall, Shrewsbury,
Shropshire, SY4 4AS.

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