

Metrobactin® Tablets for Dogs and Cats

Species:Cats, Dogs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Oral

preparations: Tablets

Active ingredient:Metronidazole

Product:Metrobactin® tablets for dogs and cats

Product index:Metrobactin tablets for dogs and cats

Qualitative and quantitative composition

Metrobactin 250 mg tablets for dogs and cats

1 tablet contains: Active substance:

Metronidazole 250 mg

Metrobactin 500 mg tablets for dogs and cats

1 tablet contains: Active substance:

Metronidazole 500 mg

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.

Clinical particulars

Target species

Dogs and cats

Indications for use

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.

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.

Adverse reactions

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

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.

Interactions

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.

Amounts to be administered and administration route

For oral administration.

The recommended dose is 50 mg metronidazole per kg body weight per day, for 5 to 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 tables are intended as a guide to dispensing the product at the recommended dose rate of 50 mg per kg body weight per day.

Metrobactin 250 mg tablets for dogs and cats dosage table:

Body weight (kg) Number of tablets daily

1 to 1.25	1/4
> 1.25 to 2.5	1/2
> 2.5 to 3.75	3/4
> 3.75 to 5	1
> 5 to 7.5	1 1/2
> 7.5 to 10	2
> 10 to 15	3
> 15 to 20	4

Metrobactin 500 mg tablets for dogs and cats dosage table:

Body weight (kg) Number of tablets daily

> 3.75 to 5	1/2
> 5 to 7.5	3/4
> 7.5 to 10	1
> 10 to 15	1 1/2
> 15 to 20	2
> 20 to 25	2 1/2
> 25 to 30	3
> 30 to 35	3 1/2
> 35 to 40	4

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.

Overdose

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.

Pharmacological particulars

Pharmacotherapeutic group: (nitro) imidazole derivatives

ATCvet code: QP51AA01, QJ01XD01

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 micro-aerophilic bacteria.

Pharmacokinetic properties

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.

Pharmaceutical particulars

Shelf life

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

Shelf life of divided tablets: 3 days

Special precautions for storage

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

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.

Disposal

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

Marketing Authorisation Holder (if different from distributor)

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

Marketing Authorisation Number

Vm 41821/4029: 250 mg

Vm 41821/4030: 500 mg

Significant changes

Date of the first authorisation or date of renewal

18 December 2015

Date of revision of the text

January 2017

Any other information

For animal treatment only. To be supplied only on veterinary prescription. Keep out of the sight and reach of children.

Legal category

Legal category:POM-V

GTIN

GTIN description:Metrobactin 250 mg Tablets for Dogs and Cats 250 tablets:

GTIN:08717973562139

GTIN description:Metrobactin 500 mg Tablets for Dogs and Cats 250 tablets:

GTIN:08717973562160

GTIN description:Metrobactin 250 mg Tablets for Dogs and Cats 10 tablets:

GTIN:08718469442089

GTIN description:Metrobactin 500 mg Tablets for Dogs and Cats 10 tablets:

GTIN:08718469442119

Dechra Veterinary Products

Telephone:01939 211200

Website:www.dechra.co.uk

Email:info.uk@dechra.com