Dechra Veterinary Products

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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

Incorporating:

Qualitative and quantitative composition

Metrobactin 250 mg tablets for dogs and cats

Each tablet contains:

Active substance:

Metronidazole 250 mg

Metrobactin 500 mg tablets for dogs and cats

Each tablet contains:

Active substance:

Metronidazole 500 mg

Excipients:

Cellulose, microcrystalline

Sodium starch glycolate, type A

Hydroxypropylcellulose

Yeast (dried)

Chicken Flavour

Magnesium stearate

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, cats.

Indications for use for each 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.).

Contraindications

Do not use in cases of hepatic disorders.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Special warnings

None.

Special precautions for safe use in the target species

Due to the likely variability (time, geographical) in the occurrence of metronidazole resistant bacteria, bacteriological sampling and susceptibility testing are recommended.

Whenever possible, the veterinary medicinal 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 may cause hypersensitivity reactions. People with known hypersensitivity to metronidazole should avoid contact with the veterinary medicinal product.

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 accidental ingestion and contact with the skin or mucous membranes including hand-to-mouth contact.

To avoid such contact wear impervious gloves when handling the veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

Adverse events

Dogs, cats:

Very rare

(<1 animal / 10,000 animals treated, including isolated reports):

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Use during pregnancy, lactation or lay

<u>Pregnancy:</u>

Studies in laboratory animals have shown inconsistent results with regard to teratogenic/embryotoxic effects of metronidazole. Therefore, use of this veterinary medicinal product during pregnancy is not recommended.

Lactation:

Metronidazole is excreted in milk and use during lactation is therefore not recommended.

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.

Amounts to be administered and administration route

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.

Symptoms of overdose (and where applicable, emergency procedures and 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.

Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

Withdrawal periods

Not applicable.

Pharmacological particulars

Pharmacotherapeutic group: Antiprotozoals, agents against protozoal diseases, nitroimidazole derivatives

ATCvet code: QP51AA01

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.

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

Major incompatibilities

Not applicable.

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.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

Marketing Authorisation Holder (if different from distributor)

Dechra Regulatory BV, Handelsweg 25, 5531 AE Bladel, The Netherlands.

Marketing Authorisation Number

Vm 50406/4016: 250 mg

Vm 50406/4017: 500 mg

Significant changes

Date of the first authorisation or date of renewal

18 December 2015

Date of revision of the text

October 2024

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 100 tablets:

GTIN:03858888794354

GTIN description: Metrobactin 500 mg Tablets for Dogs and Cats 100 tablets:

GTIN:03858888794361