PARTICULARS TO APPEAR ON THE OUTER PACKAGE Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrobactin 250 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Metronidazole 250 mg

3. PACKAGE SIZE

10 tablets
20 tablets
30 tablets
40 tablets
50 tablets
60 tablets
70 tablets
80 tablets
90 tablets
100 tablets
250 tablets
500 tablets
10 x (1 x 10) tablets
10 x (10 x 10) tablets

4. TARGET SPECIES

Dogs, cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life of divided tablets: 3 days.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

User warnings: Metronidazole may cause severe adverse reactions. Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 50406/4016

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS Aluminium-PVC/PE/PVDC blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrobactin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

250 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life of divided tablets: 3 days.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Metrobactin 250 mg tablets for dogs and cats

2. Composition

Each tablet contains:

Active substance:
Metronidazole 250 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.

3. Target species

Dogs, cats.

4. Indications for use

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.).

5. 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.

6. Special warnings

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.

Pregnancy:
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.

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.

7. Adverse events

Dogs, cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Neurological signs Vomiting Hepatic toxicosis Neutropenia

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

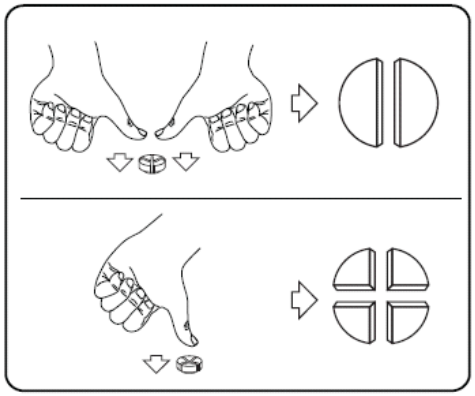
8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
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 carton and blister after Exp. The expiry date refers to the last day of that month.
Shelf life of divided tablets: 3 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50406/4016

Pack sizes:
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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

LelyPharma B.V.
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

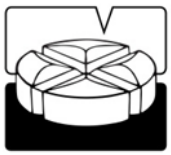
Genera d.d.
Svetonedeljska cesta 2
10436 Rakov Potok
Croatia

Local representative and contact details to report suspected adverse reactions:

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel.: +44 (0)1939 211200

17. Other information

POM-V



Divisible tablet

Gavin Hall

Approved 06 February 2024