# PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Metrocare Flavour 500 mg tablets for dogs and cats

## 2. STATEMENT OF ACTIVE SUBSTANCES
Each tablet contains 500 mg metronidazole

## 3. PACKAGE SIZE
10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 250, 500 tablets

## 4. TARGET SPECIES
Dogs and cats

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION
Oral use

## 7. WITHDRAWAL PERIOD
Not applicable

## 8. EXPIRY DATE
Exp {month/year}

## 9. SPECIAL STORAGE PRECAUTIONS
Return any divided tablet to the blister and store protected from light.

## 10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”
Read the package leaflet before use.

## 11. THE WORDS “FOR ANIMAL TREATMENT ONLY”
For animal treatment only. To be supplied only on veterinary prescription

## 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
Ecuphar
An Animalcare Company

## 14. MARKETING AUTHORISATION NUMBERS

Vm 32742/4017

## 15. BATCH NUMBER

Lot {number}

# MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {BLISTER}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Metrocare Flavour

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES
500 mg metronidazole/tablet

## 3. BATCH NUMBER
Lot {number}

## 4. EXPIRY DATE
Exp {month/year}

# PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Metrocare Flavour 500 mg tablets for dogs and cats

### 2. Composition

Each tablet contains:

**Active substance:**
Metronidazole 500 mg

White to off-white, round and convex tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 equal parts.

### 3. Target species

Dogs and cats

### 4. 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.

### 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.
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.
Metronidazole may be harmful for the unborn child.
Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product.
To avoid accidental ingestion, particularly by a child, unused part-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. 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.
Metronidazole may cause hypersensitivity reactions. People with known hypersensitivity to metronidazole should avoid contact with the veterinary medicinal product.

Pregnancy and lactation:
Studies in laboratory animals have shown inconsistent results with regards to the effects of metronidazole on embryos and during pregnancy. The use is not recommended during pregnancy. Metronidazole is excreted in milk. The use is not recommended during lactation.

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.

Major Incompatibilities:
Not applicable

## 7. Adverse events

Dogs and cats:

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Vomiting, hepatotoxicity, neutropenia, neurological signs |

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 using the contact details at the end of this leaflet, or via your national reporting system at https://www.gov.uk/report-veterinary-medicine-problem.

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

For 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 a correct dosage, body weight should be determined as accurately as possible.

| Bodyweight | Metrocare 250 mg Tablets (daily dose) | or | Metrocare 500 mg Tablets (daily dose) |
|---|---|---|---|
| 1.25 kg | ¼ | | |
| 2.5 kg | ½ | | ¼ |
| 3.75 kg | ¾ | | |
| 5 kg | 1 | | ½ |
| 7.5 kg | 1 ½ | | ¾ |
| 10 kg | 2 | | 1 |
| 15 kg | 3 | | 1 ½ |
| 20 kg | 4 | | 2 |
| 25 kg | | | 2 ½ |
| 30 kg | | | 3 |
| 35 kg | | | 3 ½ |
| 40 kg | | | 4 |

## 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 or fingers on both sides of the tablet.
Quarters: press down with your thumb or a finger in the middle of the tablet.
The remaining portion(s) should be given at the next administration(s).

## 10. Withdrawal period

Not applicable

## 11. Special storage precautions

Keep out of the sight and reach of children.
Return any divided tablet to the blister and store protected from light.

Do not use this veterinary medicinal product after the expiry date which is stated on blister and carton. The expiry date refers to the last day of that month.

## 12. Special precautions for the 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

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Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 25 or 50 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 and contact details to report suspected adverse reactions:
Ecuphar NV
Legeweg 157-i
B-8020
Oostkamp
Belgium
Tel: +32 50314269
E-mail: info@ecuphar.be

Manufacturer responsible for batch release:
Lelypharma B.V.
Zuiveringsweg 42
8243 PZ
Lelystad
The Netherlands

## 17. Other information

POM-V

*Gavin Hall*
Approved: 01 April 2025