1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrocare Flavour 500 mg tablets for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Metronidazole 500 mg

Excipients:

Qualitative composition of excipients and other constituents
Cellulose, microcrystalline
Sodium starch glycolate (type a)
Yeast extract
Hydroxypropylcellulose
Magnesium stearate

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. CLINICAL INFORMATION

3.1 Target species

Dogs and cats

3.2 Indications for use for each target species

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.

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in 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 in 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare (<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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or via the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Studies in laboratory animals have shown inconsistent results with regard to teratogenic/embryotoxic effects of metronidazole. The use is not recommended during pregnancy.

Lactation:
Metronidazole is excreted in milk. The use is not recommended during lactation.

3.8 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.

3.9 Administration route and dosage

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

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).

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

3.11 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.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01XD01

4.2 Pharmacodynamics

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 anaerobes, obligate aerobes and microaerophilic bacteria.

4.3 Pharmacokinetics

Metronidazole is immediately and well absorbed after oral administration. The peak plasma concentration, C_{max} was reached in dogs at between 0.75 and 2 hours after dosing and in cats at between 0.33 and 2 hours after dosing. The average terminal half life was 6.35 hours in dogs and 6.21 hours in cats. 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

Not applicable

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months

5.3 Special precautions for storage

Return any divided tablet to the blister and store protected from light.

5.4 Nature and composition of immediate packaging

PVC/Aluminium/Oriented polyamide /Aluminium blister packs. Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 25 or 50 blisters of 10 tablets giving pack sizes of 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 250 or 500 tablets

Not all pack sizes may be marketed.

5.5 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 or household waste.

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 system applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV

7. MARKETING AUTHORISATION NUMBER(S)

VPA10491/012/002

8. DATE OF FIRST AUTHORISATION

13/09/2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

28/04/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).