SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrotab vet. Flavoured 500 mg Tablets for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Metronidazole 500 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
Off-white to light brown with brown spots, round and convex flavoured tablet with a cross-shaped break line on one side.
The tablets can be divided into 2 or 4 equal parts.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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.
Especially after prolonged treatment with metronidazole neurological signs could occur.
As tablets are flavoured, store tablets out of reach of the animals in order to avoid accidental ingestion.

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.
Pregnant women should be careful when handling this veterinary medicinal product.
Impervious gloves should be worn during administration of the product to avoid skin and hand-to-mouth contact with the 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.
Metronidazole may cause hypersensitivity reactions. In case of known hypersensitivity to metronidazole, avoid contact with the veterinary medicinal product.
Wash hands thoroughly after handling the tablets.

4.6 Adverse reactions (frequency and seriousness)

The following adverse reactions may occur after administration of metronidazole: vomiting, hepatotoxicity and neutropenia. In very rare cases neurological signs may occur. In the dog, (cerebellovestibular) ataxia and (vertical) nystagmus were amongst the most frequently reported neurological signs.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Pregnancy
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.

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

4.8 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.

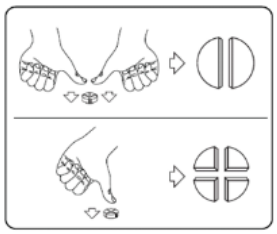
4.9 Amounts to be administered and administration route

Oral use
The recommended dose is 50 mg metronidazole per kg bodyweight (one 500 mg tablet/10 kg bodyweight) per day, for 5 - 7 days. The daily dose should preferably be divided in two equal doses 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.

	Number of tablets		
	Twice daily		**Once daily**
Bodyweight (kg)	Morning	Evening	
2.5 kg			¼
5 kg	¼	¼	½
10 kg	½	½	1
15 kg	¾	¾	1 ½
20 kg	1	1	2
25 kg	1 ¼	1 ¼	2 ½
30 kg	1 ½	1 ½	3
35 kg	1 ¾	1 ¾	3 ½
40 kg	2	2	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.



Divided tablets should be used at the next administration. Any divided tablets remaining after the last administration of the product should be discarded.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.
In literature, incidental cases of dogs suffering from metronidazole toxicosis have been described that were successfully treated with diazepam, resulting in a reduced recovery time.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals against protozoal disease, (nitro-) imidazole derivatives
ATCvet code: QP51AA01 metronidazole

5.1 Pharmacodynamic properties

Metronidazole has antiprotozoal and antibacterial activity.
After metronidazole has penetrated the bacteria the molecule is reduced by the susceptible 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 susceptible bacteria in concentrations equal to or slightly higher than the minimum inhibiting concentration (MIC).

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose, microcrystalline
Sodium starch glycolate (Type A)
Hydroxypropylcellulose
Silica, colloidal hydrated
Magnesium stearate
Chicken flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 48 months.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions. Return any divided tablet to the blister.

6.5 Nature and composition of immediate packaging

Aluminium - PVC/PE/PVDC blister in cardboard box

Package sizes:

Cardboard box with 2 blisters of 10 tablets
Cardboard box with 3 blisters of 10 tablets
Cardboard box with 5 blisters of 10 tablets
Cardboard box with 10 blisters of 10 tablets

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 20916/4040

9. DATE OF FIRST AUTHORISATION

20 May 2021

10. DATE OF REVISION OF THE TEXT

October 2023

Approved 17 October 2023