

*[Version 8.1,01/2017]*

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrotab vet. Flavoured 250 mg Tablets for dogs and cats (RMS, CMS)

Metrotab vet. 250 mg Tablet for dogs and cats (FR, ES)

Metronivet 250 mg Tablet for dogs and cats (FI, DK, SE)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

### Active substance:

Metronidazole 250 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 250 mg tablet/5 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).

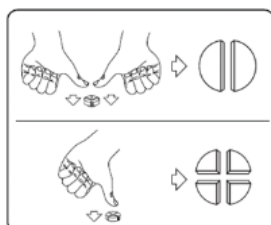
To ensure administration of the correct dosage, bodyweight should be determined as accurately as possible.

Bodyweight (kg)	Number of tablets		
	Twice daily		Once daily
	Morning	Evening	
1.25 kg			$\frac{1}{4}$
2.5 kg	$\frac{1}{4}$	$\frac{1}{4}$	$\frac{1}{2}$
5 kg	$\frac{1}{2}$	$\frac{1}{2}$	1
7.5 kg	$\frac{3}{4}$	$\frac{3}{4}$	1 $\frac{1}{2}$
10 kg	1	1	2
12.5 kg	1 $\frac{1}{4}$	1 $\frac{1}{4}$	2 $\frac{1}{2}$
15 kg	1 $\frac{1}{2}$	1 $\frac{1}{2}$	3
17.5 kg	1 $\frac{3}{4}$	1 $\frac{3}{4}$	3 $\frac{1}{2}$
20 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**

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation:

**10. DATE OF REVISION OF THE TEXT**

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**



**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton Box**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Metrotab vet. Flavoured 250 mg Tablets for dogs and cats  
Metronidazole

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains:  
Metronidazole 250 mg

**3. PHARMACEUTICAL FORM**

Tablet.

**4. PACKAGE SIZE**

20 tablets  
30 tablets  
50 tablets  
100 tablets

**5. TARGET SPECIES**

Dogs and cats.

**6. INDICATIONS**

**7. METHOD AND ROUTE OF ADMINISTRATION**

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

**9. SPECIAL WARNINGS, IF NECESSARY**

Metronidazole can cause serious adverse events. **Avoid skin contact and accidental ingestion.** Wear impervious gloves. **Store the product in a safe place.** Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

**11. SPECIAL STORAGE CONDITIONS**

Return any divided tablet to the blister.

<b>12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY</b>
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Dispose of waste material in accordance with local requirements.

<b>13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE</b>
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For animal treatment only. To be supplied only on veterinary prescription.

<b>14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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Keep out of the sight and reach of children.

<b>15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</b>
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CP-Pharma Handelsgesellschaft mbH  
Ostlandring 13  
31303 Burgdorf  
Germany

<b>16. MARKETING AUTHORISATION NUMBER</b>
---

<b>17. MANUFACTURER’S BATCH NUMBER</b>
--

Batch number:

<b>MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS</b>
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Aluminium/ PVC/ PE/PVDC blister pack
--------------------------------------

<b>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</b>
--

Metrotab vet. Flavoured 250 mg Tablets for dogs and cats  
Metronidazole

<b>2. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
--

CP-Pharma Handelsgesellschaft mbH

<b>3. EXPIRY DATE</b>
-----------------------

EXP {month/year}

<b>4. BATCH NUMBER</b>
------------------------

Batch number:

<b>5. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
---

For animal treatment only.

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET:

### Metrotab vet. Flavoured 250 mg Tablets for dogs and cats

#### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

CP-Pharma Handelsgesellschaft mbH  
Ostlandring 13  
31303 Burgdorf  
Germany

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrotab vet. Flavoured 250 mg Tablets for dogs and cats  
Metronidazole

#### 3. STATEMENT OF THE ACTIVE SUBSTANCE

Each tablet contains:

**Active substance:**

Metronidazole 250 mg

Off-white to light brown with brown spots, round and convex tablet with a cross-shaped break line on one side.

The tablets can be divided into 2 or 4 equal parts.

#### 4. INDICATIONS

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 known cases of hypersensitivity to the active substance or to any of the excipients.

#### 6. ADVERSE REACTIONS

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))
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- 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).

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 inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs and cats.

## 8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

### *Method of administration*

Oral use.

### *Dosage*

The recommended dose is 50 mg metronidazole per kg bodyweight (one 250 mg tablet/5 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.

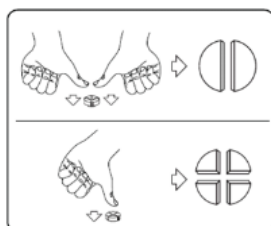
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17.5 kg	1 $\frac{3}{4}$	1 $\frac{3}{4}$	3 $\frac{1}{2}$
20 kg	2	2	4

## 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.



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

## **10. WITHDRAWAL PERIOD**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.  
Any remaining tablet portion should be returned to the blister and given at the next administration.  
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.

## **12. SPECIAL WARNINGS**

Special warnings for each target species:  
None.

### 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.

### Pregnancy and lactation:

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.

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 (symptoms, 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.

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.

Major incompatibilities:

Not applicable.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

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.



**België/Belgique/Belgien**

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info@cp-pharma.de.

**Danmark**

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