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 1000 mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Metronidazole 1000 mg

3. PACKAGE SIZE

10 tablets
20 tablets
30 tablets
50 tablets
100 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Return any divided tablet to the blister.

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

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.

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

CP Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

Vm 20916/4041

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Aluminium- PVC/ PE/PVDC blister pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrotab vet. Flavoured 1000 mg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Metronidazole 1000 mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Metrotab vet. Flavoured 1000 mg Tablets for dogs

2. Composition

Each tablet contains:

Active substance:
Metronidazole 1000 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.

3. Target species

Dogs

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 warnings:

None.

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 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. People with known hypersensitivity to metronidazole should avoid contact with the veterinary medicinal product.
Wash hands thoroughly after handling the tablets.

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.

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.
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.

7. Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Neurological signs (e.g. ataxia[1,2], nystagmus[1,3])
Undetermined frequency (cannot be estimated from the available data)	Vomiting Hepatic toxicosis (liver disorder) Neutropenia (low levels of neutrophils)

[1] Amongst the most frequently reported neurological signs
[2] Cerebellovestibular ataxia (coordination disorder)
[3] Vertical nystagmus (involuntary eye movements)

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 its local representative using the contact details at the end of this leaflet, or via your national reporting system:
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 (one 1000 mg tablet/20 kg bodyweight) per day, for 5 - 7 days.

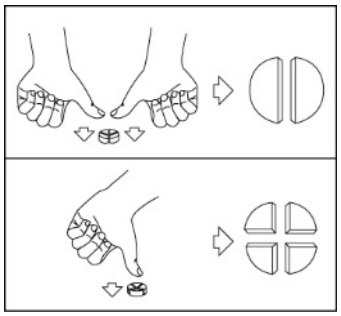
The daily dose should preferably be divided in two equal doses for twice daily administration (i.e. 25 mg/kg bodyweight twice daily).

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

	Number of tablets		
	Twice daily		Once daily
Bodyweight (kg)	Morning	Evening	
5 kg			¼
10 kg	¼	¼	½
20 kg	½	½	1
30 kg	¾	¾	1 ½
40 kg	1	1	2
50 kg	1 ¼	1 ¼	2 ½
60 kg	1 ½	1 ½	3
70 kg	1 ¾	1 ¾	3 ½
80 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 periods

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 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 20916/4041

Blister containing 10 tablets each.

Package sizes:

Cardboard box with 1, 2, 3, 5 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 <,> <and> <manufacturer responsible for batch release> <and contact details to report suspected adverse events>:

CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany
Tel: +49-(0)5136-6066-0

Local representatives and contact details to report suspected adverse events:

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Gavin Hall
Approved: 01 July 2026