ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrocare Flavour 250 mg tablets for dogs and cats
Metronidazole

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 250 mg metronidazole

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 250, 500 tablets

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

IMPERVIOUS GLOVES SHOULD BE WORN. Store the product in a safe place. Avoid skin contact and accidental ingestion. Metronidazole may cause severe adverse reactions.
Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
B-8020
Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32742/4016

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrocare Flavour 250 mg tablets for dogs and cats
Metronidazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV

3. EXPIRY DATE

<EXP {month/year}>

4. BATCH NUMBER

<Batch><Lot> {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Metrocare 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
Ecuphar NV
Legeweg 157-i
B-8020
Oostkamp
Belgium

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrocare Flavour 250 mg tablets for dogs and cats
Metronidazole

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each tablet contains:

Active substance: Metronidazole 250 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.

4. INDICATION(S)

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. ADVERSE REACTIONS

The following adverse reactions may occur after administration of metronidazole: vomiting, hepatotoxicity, neutropenia and 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)
-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).

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(S) AND METHOD OF ADMINISTRATION

For oral administration.
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 administration of the correct dosage, bodyweight 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 after the expiry date stated on blister and carton.

12. SPECIAL WARNING(S)

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.
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.
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. Wash hands thoroughly after handling the tablets.
Metronidazole may cause hypersensitivity reactions. In case of known hypersensitivity to metronidazole, avoid contact with the veterinary medicinal product.

Use during Pregnancy and lactation:

Studies in laboratory animals have shown inconsistent results with regards to the effects of metronidazole on embryos and during pregnancy. 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.

Major Incompatibilities:

Not applicable

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

Approved 23 September 2019