ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE CARDBOARD BOX OF 1, 2, 5, 10, 25 OR 50 BLISTERS OF 8 TABLETS

{CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrovis 750 mg tablets for dogs
Metronidazole

2. STATEMENT OF ACTIVE SUBSTANCES

Metronidazole 750 mg.

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

8 tablets
16 tablets
40 tablets
80 tablets
200 tablets
400 tablets

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Metronidazole may cause severe adverse reactions and has been associated with carcinogenicity. Avoid skin contact and accidental ingestion. Wear gloves. Store the product in a safe place. See package leaflet for full user warnings.

10. EXPIRY DATE

<EXP {month/year}>
Shelf life of divided tablets: 3 days

11. SPECIAL STORAGE CONDITIONS

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

Livisto Int'l S.L.
Av. Universitat Autònoma 29
08290 Cerdanyola del Vallès
(Barcelona) Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43173/4015

17. MANUFACTURER’S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

{ALUMINIUM - PVC/PE/PVDC BLISTER CONTAINING 10 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrovis 750 mg tablets.
Metronidazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Livisto Int'l S.L.

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:

{Metrovis 750 mg tablets for dogs}

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

Marketing authorisation holder:
Livisto Int'l S.L.
Av. Universitat Autònoma 29
08290 Cerdanyola del Vallès
(Barcelona) Spain

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

OR

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

OR

Industrial Veterinaria S.A.
Esmeralda 19, Esplugues de Llobregat
08950 Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrovis 750 mg tablets for dogs
Metronidazole

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

1 tablet contains:
Active substance:
Metronidazole 750 mg
Beige coloured, round tablets 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 case of hepatic disorders.
Do not use in case 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(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).

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. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use.
The recommended dose is 50 mg metronidazole per kg bodyweight per day, for 5-7 days. The daily dose may be split into two administrations per day (i.e. 25 mg/kg bodyweight twice daily).

To ensure administration of the correct dosage, bodyweight should be determined as accurately as possible. The following table is intended as a guide to dispensing the product at the recommended dose rate of either 50 mg per kg bodyweight, administered once daily or, preferably administered twice daily in 25 mg per kg bodyweight.

	Number of tablets		
	Twice daily		Once daily
Bodyweight (kg)	Morning	Evening	
7.5 kg	¼	¼	½
15 kg	½	½	1
22.5 kg	¾	¾	1 ½
30 kg	1	1	2
37.5 kg	1 ¼	1 ¼	2 ½
45 kg	1 ½	1 ½	3
52.5 kg	1 ¾	1 ¾	3 ½
60 kg	2	2	4
67.5 kg	2 ¼	2 ¼	4 ½
75 kg	2 ½	2 ½	5

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 on both sides of the tablet.
Quarters: press down with your thumb in the middle of the tablet.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
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.
Shelf life of divided tablets: 3 days

12. SPECIAL WARNING(S)

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 contact with the product.

To avoid accidental ingestion, particularly by a child, unused tablets and part-tablets should be returned to the open blister space, inserted back into 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.

Pregnancy:
Studies in laboratory animals have shown inconsistent results with regard to teratogenic/embryotoxic effects of metronidazole. Therefore, the 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 (symptoms, emergency procedures, antidotes):
Adverse events are more likely to occur at doses and treatment durations in excess of the recommended treatment regimen. If neurologic signs occur, treatment should be discontinued, and the patient should be treated symptomatically.

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, 5, 10, 25 or 50 blisters of 8 tablets.
Not all pack sizes may be marketed.

Approved 28 November 2023