ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing a bottle of 30 ml or 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERADIA 125 mg/ml oral suspension for dogs
Metronidazole

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 125 mg metronidazole.

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

30 ml.
100 ml.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

…. ml/ …. times per day/for …. days.

Pour over a part of the feed and wait until the dog has completely consumed it or administer directly into the dog's mouth wearing gloves.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

May be harmful for the user. Avoid oral ingestion and contact with skin.
Pour over a part of the feed and wait until the dog has completely consumed it or administer directly into the dog's mouth wearing gloves. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 3 months.
Once opened, use within 6 months.

11. SPECIAL STORAGE CONDITIONS

Store below 30° C.

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

VIRBAC
1ère avenue – 2065m – LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER

Vm 05653/5044

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 30 ml or 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERADIA 125 mg/ml oral suspension for dogs
Metronidazole

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

125 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

30 ml
100 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use within 3 months.
Once opened, use within 6 months.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

ERADIA 125 mg/ml oral suspension 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:
VIRBAC
1ère avenue – 2065m – LID
06516 Carros
France

Manufacturer responsible for batch release:
VIRBAC
1ère avenue – 2065m – LID
06516 Carros
France

DELPHARM Huningue
26 rue de Chapelle
68330 Huningue
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERADIA 125 mg/ml oral suspension for dogs
Metronidazole

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

Each ml contains

Active substance:
Metronidazole 125 mg

Excipients:
Butylhydroxytoluene (E321) 0.2 mg

Flavoured oily suspension with brown visible particles

4. INDICATION(S)

Treatment of infections of the gastrointestinal tract caused by *Giardia* spp. and *Clostridium* 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. *Clostridium* 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 and neutropenia.
In very rare cases, neurological signs may occur especially after prolonged treatment with metronidazole.

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.

7. TARGET SPECIES

Dogs.

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

Oral use.
The recommended dose is 50 mg metronidazole per kg bodyweight per day (i.e. 0.4 mL per kg bodyweight), preferably given in two equally divided doses (i.e. 25 mg equivalent to 0.2 mL per kg bodyweight twice daily) for 5-7 days.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing and overdosing.

The following table is intended as a guide to dispensing the product at the volume corresponding to either 25 mg/kg for administration twice daily or 50 mg/kg for administration once daily.

Examples of bodyweight (kg)	Volume to administer twice daily for 25mg/kg	Volume to administer once daily for 50mg/kg
1		0.4mL
2	0.4mL	0.8mL
3	0.6mL	1.2mL
4	0.8mL	1.6mL
5	1.0mL	2.0mL
10	2.0mL	4.0mL
15	3.0mL	6.0mL
20	4.0mL	8.0mL
25	5.0mL	10.0mL
30	6.0mL	12.0mL
35	7.0mL	14.0mL
40	8.0mL	16.0mL

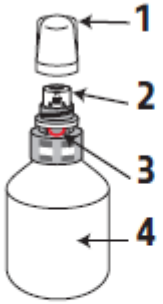
For doses requiring more than two filled syringes, the dosing should be twice daily in order to minimize counting and dosing errors.

The oral suspension is delivered through the package described below

9. ADVICE ON CORRECT ADMINISTRATION

[Snap cap packaging]
A - Shake the bottle vigorously before use.
B - Unscrew the protective overcap.
C - Insert the syringe into the upper white part of the cap (finger-grip) **by pushing firmly**, then, while pushing, turn the syringe to the right (clockwise) until the green smile appears.
D - Turn the bottle upside down and withdraw the prescribed volume of the product, in the upside down position.
E - Once the correct volume of the product has been drawn into the syringe, unscrew the syringe from the cap **without pushing** by turning it to the left (counterclockwise) until the red smile appears again, then continue to turn in order to unfasten the syringe.
The system can also be closed by turning the finger-grip manually.
F - Screw the protective overcap back on.
Administer the product by pouring it over a part of the feed or by direct administration into the animal's mouth. Wear impervious gloves when handling the product and/or administering the product into the animal's mouth.
When administered over the feed, wait until the animal has completely consumed the medicated feed, then administer the rest of the feed.

PRODUCT DESCRIPTION



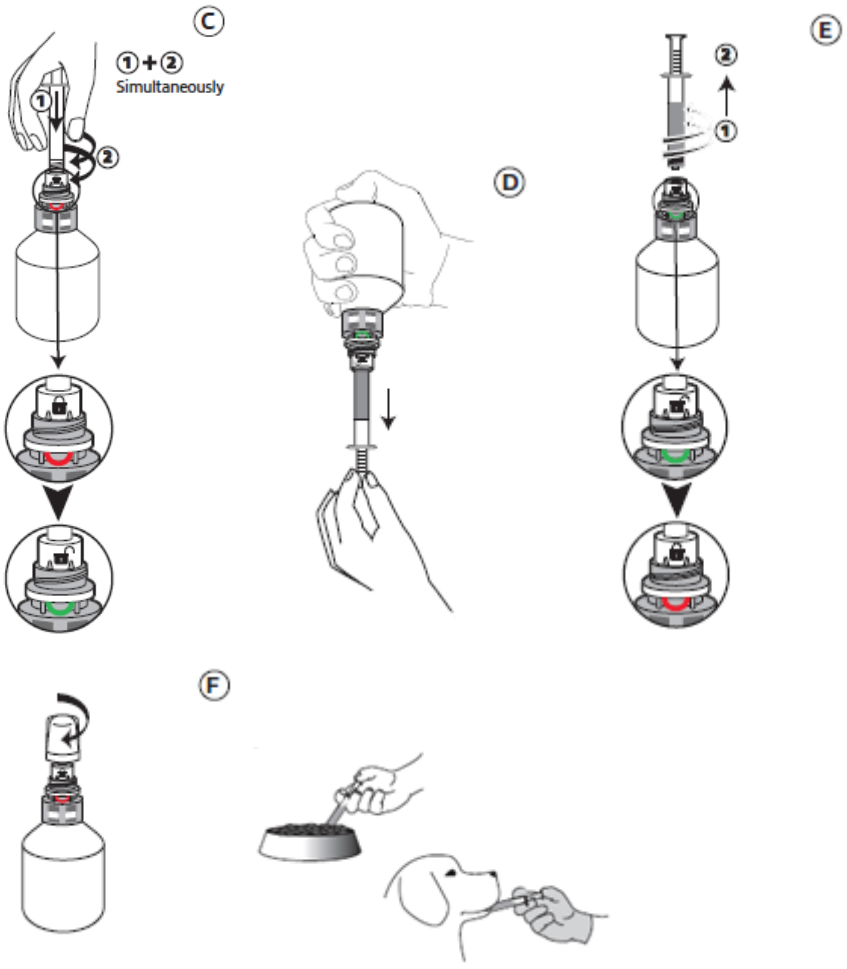
Dosing syringe

1 Protective overcap

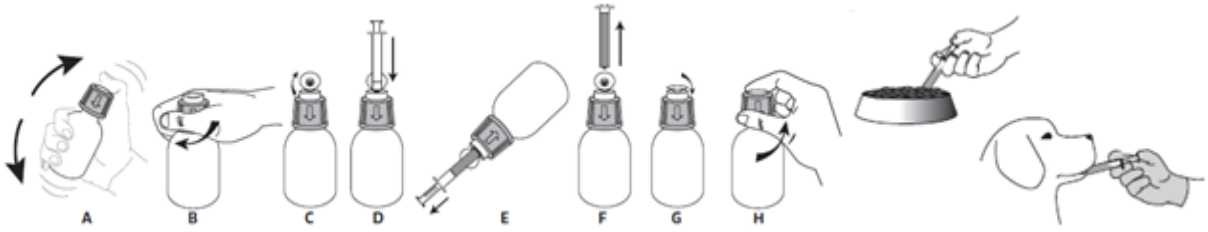
2 Delivery system = finger grip allowing the syringe to be screwed into place and the system to be opened by rotation

3 Colored smile: red = closed / green = open

4 Bottle



[Screw cap packaging]
A-Shake vigorously the bottle before use.
B-Push down strongly and turn right the colored part of the cap until it is locked.
C-Open the hindge flap.
D-Plug the syringe on the bottle in upright position.
E-Turn over the bottle and sample the prescribed volume of the product in upside down position.
F-Once filled, turn over the bottle. Unplug the syringe in upright position.
G-Close the hindge flap.
H-Turn left and pull up the colored part of the cap.
Administer the product by pouring it over a part of the feed or by direct administration into the animal's mouth. Wear impervious gloves when handling the product and/or administering the product into the animal's mouth.
When administered over the feed, wait until the animal has completely consumed the medicated feed, then administer the rest of the feed.



NOTE : The package leaflet on the market shall mention either the snap cap packaging or the screw cap packaging but not both.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 30° C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging:

- 30 ml bottle: 3 months.
- 100 ml bottle: 6 months.

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.

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 thus may have carcinogenic effects in humans as well. However, there is inadequate evidence in humans for the carcinogenicity of metronidazole.

The product can cause skin sensitisation. In case of known hypersensitivity to metronidazole or other nitroimidazole derivatives or one of the components of the product, avoid contact with the veterinary medicinal product.
Avoid contact with the skin or mucous membranes included hand-to-mouth contact.
To avoid such contact wear impervious gloves when handling the product and/or for direct administration into the animal's mouth.
Do not allow treated dogs to lick persons immediately after intake of the medication.
Wash hands after use.
In case of skin contact, wash thoroughly the affected area.

Metronidazole may cause adverse (neurological) effects.
Avoid accidental ingestion.
Do not drink, eat or smoke when administering the product.
Close the bottle immediately after use to avoid the child gaining access to the contents. Do not leave a syringe containing solution in the sight or reach of children. In order to prevent children from getting access to used syringes, keep the syringes in the original packaging after use.
In case of accidental ingestion, seek-medical advice immediately and show the package leaflet or the label to physician

Additional warnings when administering the product into the feed:
Avoid the access of children to the dog’s medicated food. In order to prevent children from getting access to the dog’s medicated food, pour it over a part of the feed and wait until the animal has completely consumed the medicated feed, then administer the rest of the feed. Give the treatment out of the sight and reach of children. Any uneaten medicated food must be removed immediately and the bowl washed thoroughly; wear gloves and wash hands when handling the product and cleaning the contaminated food bowl.

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.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

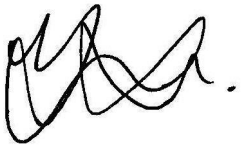
13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

Bottle of 30 ml or 100 ml.
Not all pack sizes may be marketed.



Approved: 23 April 2024