PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboardbox}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrovis 750 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Metronidazole 750 mg.

3. PACKAGE SIZE

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

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life of divided tablets: 3 days

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “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.
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

Industrial Veterinaria SA

14. MARKETING AUTHORISATION NUMBERS

Vm 36547/3017
Vm 36547/5017

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metrovis

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

750 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Metrovis 750 mg tablets for dogs

2. Composition

Each 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.

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 case 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 veterinary medicinal 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.
Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal 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 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.

Pregnancy:
Studies in laboratory animals have shown inconsistent results with regard to teratogenic/embryotoxic effects of metronidazole. Therefore, the use of this veterinary medicinal 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 neurologic signs occur, treatment should be discontinued, and the patient should be treated symptomatically.

7. Adverse events

Dogs:

Undetermined frequency (cannot be estimated from the available data):
Vomiting
Hepatic toxicosis
Neutropenia
Neurological signs

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

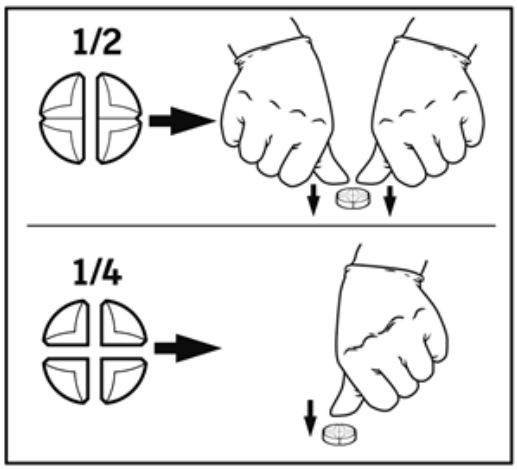
Oral use.
The recommended dose is 50 mg metronidazole per kg bodyweight per day, for 5-7 days. The daily dose may be split into two administrations per day (i.e. 25 mg/kg bodyweight twice daily).

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 veterinary medicinal 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.

Bodyweight (kg)	Number of tablets		
	Twice daily		Once daily
	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 periods

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 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 36547/3017
Vm 36547/5017

Cardboard box of 1, 2, 5, 10, 25 or 50 blisters of 8 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:
Industrial Veterinaria SA
Calle Esmeralda, 19
08950 Esplugues de Llobregat
Spain

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

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Industrial Veterinaria SA
Calle Esmeralda, 19
08950 Esplugues de Llobregat
Spain

Local representatives and contact details to report suspected adverse events:
FORTE Healthcare Limited
Block 3, Unit 9
CityNorth Business Campus
Stamullen, Co.
Meath. K32 D990
Republic of Ireland
Tel.: +353 1 841 7666
E-Mail: pharmacovigilance@fortehealthcare.com

17. Other information

POM-V

Gavin Hall
Approved: 09 April 2026