Veterinary Physician's Prescribing Information

STOMORGYL 10 VETERINARY

1. TRADE NAME OF MEDICINAL PRODUCT
STOMORGYL 10 VETERINARY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains: Spiramycin 750,000 IU and Metronidazole 125 mg

Excipients: Colorants: Cochnieal Red A and Titanium dioxide.
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Film-coated tablet. Pink circular convex scored tablet.

4. CLINICAL PARTICULARS
4.1 Target species: Dogs and cats.

4.2 Indications for use, specifying the target species:
Infection due to sensitive aerobic and anaerobic bacteria, especially infections of oral cavity: stomatitis, gingivitis, periodontal disease, pyorrhoea halitosis. In dogs and cats.

4.3 Contraindications:
Do not use in animals with a known hypersensitivity to spiramycin or metronidazole.

4.4 Special warnings (for each target species): None known.

4.5 Special precautions for use:
Special precautions for use in animals: None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals: In case of accidental ingestion obtain medical advice if needed. Wash hands after use. Should direct skin contact occur, wash affected area. Should accidental eye exposure occur, flush the eyes immediately with water and seek medical attention if needed.

4.6 Adverse reactions (frequency and seriousness): Some very rare cases of digestive disorders (vomiting, diarrhea, anorexia) may be observed after treatment.
A brown coloration of the urine may be observed.

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).

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit / risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:
https://sideeffects.health.gov.il /

4.7 Use during pregnancy, lactation or lay: Safety in pregnant dogs and cats has not been demonstrated.

4.8 Interaction with other medicinal products and other forms of interaction: The product should not be used concurrently with other antibiotics of the macrolide group.

4.9 Amounts to be administered and administration route:
By oral administration. For dogs and cats, 75,000 IU spiramycin and 12.5 mg metronidazole / kg bodyweight, once daily for 5 to 10 days.
Equivalent to: 1 tablet / 10 kg bodyweight once daily for 5-10 days.
Do not break or crush the tablets.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary: No signs of toxicity were seen in cats receiving 5 times the recommended dose, or in dogs receiving 8 times the recommended dose.

4.11 Withdrawal period(s): Not applicable.

5. PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: Antibacterials for systemic use, combinations of antibacterials.
ATCVet code: QJ01RA04

5.1 Pharmacodynamic properties:
The product is a combination of two antibiotics: spiramycin and metronidazole. Metronidazole has antimicrobial activity against most anaerobes, including *Bacteroides*, *Fusobacterium* and spirochaetes. Spiramycin has a therapeutic spectrum including Gram-positive aerobes such as staphylococci, streptococci and *Bacillus*, but also including anaerobes such as *Actinomyces*, *Clostridium* and *Bacteroides*. Antimicrobial synergy has been shown *in vitro* for many of these organisms.

5.2 Pharmacokinetic particulars:
After oral administration, plasma spiramycin concentrations reach their maximum between 2 and 4 hours after administration (C_{max} = 2.29 IU / mL after repeated administration) and saliva concentrations between 4 and 8 hours. Saliva concentrations are approximately 3 times higher than plasma concentrations (C_{max} = 2.86 IU / mL after repeated administration). Maximum plasma concentrations for metronidazole are reached 1 hour after administration in saliva and are of the same order of magnitude as plasma concentrations (C_{max} = 7.07 µg / mL after repeated administration).

The volume of distribution (V_d) is 7.84 L / kg for spiramycin and 0.7 L / kg for metronidazole. The terminal plasma half-life ($t_{1/2}$) is 8.10 hours for spiramycin and 5.69 hours for metronidazole respectively. Plasma clearance is 0.823 L / h / kg for spiramycin and 0.081 L / h / kg for metronidazole. The main route of elimination is bile for spiramycin while metronidazole is excreted through faeces and urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients: Wheat Starch, Aluminium Oxide Hydrated, Sorbitol, Dextrin, Gelatin, Citric Acid Monohydrate, Magnesium Stearate, Hypromellose, Polyoxyethylene Glycol 20000, Cochnieal Red A, Titanium Dioxide.

6.2 Major incompatibilities: None known.

6.3 Shelf life: The expiry date of the product is indicated on the label and packaging. Do not use after the expiry date.

6.4 Special precautions for storage: Store below 25°C.

6.5 Nature and composition of immediate packaging: Opaque, white, non-plasticised polyvinylchloride-acetochloride blister pack with aluminium foil backing containing 10 tablets per strip. The number of blister strips per cardboard box may vary between 1 to 5 (i.e., total of 10 tablets to 50 tablets).
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate: Any unused product or waste material should be disposed of in accordance with national requirements.

7. Israeli Drug Registration Number: 082-54-92302-00

8. Manufacturer: Boehringer Ingelheim Animal Health France SCS, Lyon, France.

9. Israeli Marketing Authorization Holder: Beit Erez Havat Milatin, P.O.B. 209, Mishmar Hashiva 50297, Israel.

10) REVISED ON: 11/2021 according to MOH's guidelines.
[Internal code: STMGL-10-VET-DCTR-11/21 dated 01/11/2021]