

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

Veterinary medicine package leaflet

This medicine is dispensed with a veterinarian's prescription only

For use in animals only

1) Name, form and strength of the veterinary medicine:

Stomorgyl 10 veterinary

Film-coated tablets for dogs and cats.

2) Name and quantity in dosage unit of the active ingredients:

Each film-coated tablet contains: Spiramycin 750,000 IU (international units) and 125 mg Metronidazole.

Important excipients: the colorants Cochineal red A and Titanium Dioxide.

This medicine contains wheat starch (contains gluten).

For a list of all inactive ingredients and allergens in this medicine - see section 13.

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, consult your veterinarian or pharmacist.

3) What is this medicine intended for?

This medicine is intended for treating infections and inflammation caused by aerobic and anaerobic bacteria in dogs and cats, especially inflammations of the gums and teeth, and oral cavity infections (Stomatitis, Gingivitis, Periodontal disease and Pyorrhea halitosis).

Therapeutic group: Spiramycin: a macrolide antibiotic. Metronidazole: nitroimidazole antibiotic for treating infections caused by anaerobic bacteria and by protozoa.

4) Contraindications:

Do not use this medicine:

- if the dog / cat is sensitive (allergic) to the active ingredients or to any of the other ingredients in this medicine.
The active ingredients are listed in section 2 and the additional ingredients are listed in section 13.
- This medicinal product contains gluten from the excipient Wheat Starch - do not use in animals that are sensitive to gluten.

5) Side effects:

Like with all medicines, using this medicine may cause side effects in some dogs / cats. Do not be alarmed by this list of side effects; your dog / cat may not experience any of them.

The following side effects have been observed rarely after administration of the medicine:

- in the digestive tract (vomiting, diarrhea, anorexia).
- weakness.
- urine color may become brown.

If any side effect gets worse, or if the dog / cat experiences a side effect not mentioned in this leaflet, consult your veterinarian.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

6) Target species:

This medicine is for use in dogs and cats only.

7) Dosage and method of administration:

Always use this medicine according to your veterinarian's instructions. Check with your veterinarian or pharmacist if you are not sure. Only your veterinarian will determine the dose and how this medicine should be administered.

Before administration of this treatment, consult your veterinarian to make sure this is the correct medicine for the dog / cat's medical diagnosis.

Do not exceed the recommended dose.

Route of administration: tablets for swallowing.

Dosage: Use this medicine at regular times, as prescribed by your veterinarian.

One tablet per 10 kg animal body weight per day (this means 12.5 mg / kg / day of metronidazole and 75,000 IU / kg / day of spiramycin) for 5-10 days.

Complete the animal's course of treatment as recommended by your veterinarian.

8) How to use this medicine:

- Do not split, crush or break the tablet.
- Wash hands after use.

9) Withdrawal period:

Withdrawal periods before slaughter: not applicable. This medicine is for use in dogs and cats only.

10) Warnings:

- **Special warnings about use in the target animal:** none.
- **Special warnings about the safety of using this medicine in animals:** none.
- **Special safety precautions for the person administering the medicine:** If a person has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. In case of skin contact, wash the area. In case of contact with the eye, flush the eye with water immediately and get medical assistance if necessary.
- **Pregnant and lactating animals:** Safety of use in pregnant dogs / cats has not been demonstrated. Consult your veterinarian before use, if this is the case.
- **Drug interactions and other interactions:** Do not use concomitantly with other macrolide antibiotics.
- **Overdose:** No signs of toxicity were seen in cats receiving 5 times the recommended dose, or in dogs receiving 8 times the recommended dose.
- **Incompatibility:** none known.

11) Storage instructions:

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants.
- Do not use the medicine after the expiry date (Exp. Date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.

12) Instructions for the disposal of unused medicine or waste materials:

- Do not throw away any medicines in the toilet or with household waste.
- Ask your pharmacist or veterinarian how to dispose of medicines that have expired or that you no longer use. These measures will help protect the environment.

13) Additional information:

- **In addition to the active ingredients, this medicine also contains the following inactive ingredients:** Wheat Starch, Aluminum Oxide Hydrated, Sorbitol, Dextrin, Gelatin, Citric Acid Monohydrate, Magnesium Stearate, Hypromellose, Polyoxyethylene Glycol 20,000, Cochineal Red A, Titanium Dioxide.
- **What the medicine looks like and contents of the pack:** The medicine is a round, convex, pink, film-coated tablet with a score line. Do not split, crush or break the tablet.
- The tablets are packaged in plastic strips (blister trays) which are packed in a box.
- **Pack size:** blister strip(s) with 10 tablets per strip. The number of blister strips in a box may vary, depending on pack size.
- The number of tablets in the pack is listed on the carton.
- Not all pack sizes may be marketed.
- **Registration holder:** Beit-Erez Havat Milatin Ltd., POB 209, Mishmar Hashiva 50297.
- **Manufacturer:** Boehringer Ingelheim Animal Health France, Lyon, France.

This medicine is intended for male and female dogs and cats.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 082-54-92302-00.

Revised in: 11/2021 according to MOH guidelines.