CONSUMER LEAFLET FOR A VETERINARY PRODUCT

This medicine is marketed solely according to a veterinarian's prescription

MILPRO 12.5 mg / 125 mg veterinary
Coated tablets for dogs

1) Name of the medicine, form and strength:

Name of the medicine: MILPRO 12.5 mg / 125 mg veterinary

Pharmaceutical form: Coated tablets

2) Active substance and its content per dose unit:

The active substances and their quantity in each tablet: Milbemycin Oxime 12.5 mg and Praziquantel 125 mg

For the list of inactive excipients and allergenic substances – see Section 13.

Please read this leaflet carefully until the end prior to using the medicine. This leaflet includes concise information about this medicine. If you have additional questions, please refer to the veterinarian or pharmacist.

3) What is the medicine intended for?

The medicine is intended for dogs, for the treatment of mixed infection by tapeworms (cestodes) and roundworms (nematodes) of the following species:

- Cestodes: *Dipylidium caninum, teania* species, *echinococcus* species and *mesocestoides* species
- Nematodes: *Ancylostoma caninum, Toxocara canis, Toxascarins leonina, Trichuris vulpis, Thelazia callipaeda,* -Crenosoma vulpis-reduction of the level of infection *and Angiostongylus vasorum* - reduction of the level of infection by immature adult (L5) and adult parasite stages.
- It is also possible to use the product for the prevention of heartworm disease caused by *Dirofilaria immitis*, if concomitant treatment against tapeworms is also required.

Therapeutic group:

- Milbemycin Oxime belongs to the family of macrocyclic lactones. These substances affect the chloride balance of the worms and parasites cells and lead to their death.

- Praziquantel is a derivative of isoquinoline (acylated pyrazino-isoquinoline derivative). The substance affects the calcium balance of the worms and parasites cells and leads to their death.

4) Contraindications:

Do not use the medicine:

- If the dog is sensitive (allergic) to the active substances or to any of the excipients included in the product. The active substances are listed in Section 1 and the excipients in Section 13.
- In dogs weighing less than 5 kg.

5) Side effects:

As for any medicine, the use of this product may cause side effects in some of the treated dogs. Do not be alarmed when reading the list of side effects. Your dog might not suffer from any of them.
Very rare side effects: Apathy, excessive tiredness, muscular tremor, lack of muscle control, vomiting, drooling, diarrhea, anorexia.
If any of these side effects becomes more severe or if the dog exhibits a side effect not mentioned in the leaflet, consult the veterinarian.

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects. Alternatively you can use the following link: /https://sideeffects.health.gov.il

6) Target animals

The medicine is intended solely for use in dogs.

7) Dosage and administration

Always use according to the veterinarian's instructions. If you are not sure, check with a veterinarian or pharmacist. The dosage and course of treatment will be determined only by the veterinarian.
Do not exceed the recommended dose.

Dosage form: Oral tablets.

Dosage: It is important to weigh the dog in order to administer the accurate dosage. The minimum recommended dose is Milbemycin Oxime 0.5 mg/kg body weight and Praziquantel 5 mg/kg body weight for each kg of the dog's body weight, in a single administration.
The usual dosage by weight is:
Dog weighing 5 - 25 kg: one tablet
Dog weighing >25 -50 kg: two tablets

Dog weighing >50 - 75 kg: three tablets

Frequency of administration: Treatment should be continued as recommended by the veterinarian.

- If there is a need for tapeworms treatment and also for preventive heartworm treatment: the product can be given as combined treatment for both infections instead of treatment with a different medicine for heartworm prevention.
- Treatment for nematodes of the Angiostrongylus vasorum species: for a single infection, treatment should be with a product containing one component, Milbemycime Oxime alone, once weekly for 4 weeks. for infection mixed with tapeworms, it is recommended to give the first dose of this product, i.e. Milpro, and then to continue with additional 3 doses of the product containing Milbemycine Oxime only, at the recommended dosage.
- In endemic areas of Angiostrongylus vasorum nematodes and of tapeworms contamination, administration once every 4 weeks will prevent development of worms and parasites in the dog.
- Treatment for roundworms of the Thelazia callipaeda species: for a single infection, treatment requires using a product containing Milbemycine Oxime only. The medicine should be administered twice with 7 days interval. In mixed infection with tapeworms, the product containing Milbemycine Oxime only can be replaced by this product (Milpro).

Repeated treatment in the dog: To be determined by the veterinarian according to reasonability assessment of the presence of contamination or a recurrent infection of the dog by worms and parasites.
Do not give the medicine in the dark! Check the label and dose each time you give the medicine to the dog. Wear glasses if you need them. If you have additional questions regarding the use of this medicine, consult the veterinarian or a pharmacist.

8) Method of administration

- The tablet should be given to the dog with food or after a meal.
- The tablets are meat flavored and usually tasty for most of thedogs.
- Usually, the dog will agree to swallow the tablet even without food.
- The tablets must not be cut in half.

9) Withdrawal period:

Withdrawal period before slaughter: Not applicable. The medicine is intended for dogs only.

10) Warnings

- **Special warning for use in the target species:** Special attention is required when treating Collie dogs and similar species. In these species, the therapeutic range of the drug is narrower, and it is therefore recommended to follow closely the recommended dosage and to follow the condition of the dog. There is lack of information regarding the use of this medicine in puppies of this species. The clinical symptoms in this species are similar to those observed in the general dogs population.
- Treatment in high-grade infection with nematode species in the microfilariae stage can cause symptoms of hypersensitivity, such as: pale mucosa (in the mouth, nose, etc.), vomiting, tremor, accelerated breathing or drooling. These symptoms are caused by the penetration into the bloodstream of various proteins from the dead nematode species. Therefore, using the drug in dogs with a high rate of infection of nematode species in their early life cycle stages is not recommended.
- The medicine is not recommended in severely debilitated dogs or in dogs having severely impaired renal or liver function, because no studies have been performed in these groups. The treating veterinarian must carefully weigh the risk against the benefit of using the medicine in such cases.
- Treatment of mixed tapeworm and roundworm infection in dogs younger than 4 weeks is generally not required, because tapeworm infection is unusual in this age group.
- **Special warnings for the safety of use in animals:** If a dog was in an endemic heartworm region, consult a veterinarian prior to initiating treatment with the medicine, in order to exclude a concomitant infection with heartworm *(Dirofilaria immitis*). If a concomitant infection with heartworm is present, this must be treated first, and only after that start the treatment with Milpro.
- In order to achieve optimal long-term efficacy against worms and parasites, local epidemiologic data and the dog's living environment should be taken into account. Consult with professional entities regarding measures to be taken to prevent a recurrent infection in the dog.
- Frequent use of the medicine may lead to the development of resistance to the active substances in worms and parasites.
- **Special precautions regarding safety of persons treating with the medicine:** Tapeworms of Echinococcosis species are dangerous to humans. In the event of infection of the dog with this species, special guidelines for treatment and follow-up of the animal and safety measures for the treating person must be strictly followed. Relevant institutions and professional parasitologists must be consulted. If the dog was staying in a region infected by Echinococcosis species tapeworms, consult a veterinarian.
  To prevent children from coming in contact with the medicine, only one tablet should be removed from the package at a time. After removing the

tablet, replace the blister pack with the remaining tablets into the carton package.

If a person swallowed the medicine by mistake, especially a child, refer immediately to a doctor or a hospital emergency room and bring the product package with you.

Wash your hands after handling the medicine.

- **Pregnancy and lactation:** The medicine was tested and found to be safe for use during pregnancy and lactation.
- **Interactions with other medicines and other types of interactions:** Unknown. It is possible to use this medicine together with drugs containing the active substance Selamectin.

  If the dog receives or has recently received other medicines or products (including products for external or internal parasites), report this to the veterinarian or pharmacist.
- **Overdose:** No additional signs except for those observed in the recommended dosages were observed.
- **Incompatibility**: Unknown.

11) Instructions for storage:

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of reach of children and/or infants to avoid poisoning.
- The medicine must not be used after the expiry date (Exp. Date) shown on the package. The expiry date refers to the last day of the month indicated.
- **Storage conditions:** Store at temperature below 30^{o}C.

12) Instructions for the disposal of the medicinal product or its residues after use:

- The medicine is toxic for fish and aquatic animals.
- The medicine may not be discarded into the toilet, water sources, sewage system or with the domestic waste. Make sure that the medicine and its empty package does not come in contact with water sources. Ask your pharmacist or your veterinarian how to dispose of any medicine that has expired or is no longer needed. These measures will help protect the environment.

13) Additional information:

- **In addition to the active substance, the medicine contains the following inactive excipients:**

  Microcrystalline Cellulose, Croscarmellose Sodium, Lactose Monohydrate, Pregelatinized Starch, Povidone, Magnesium Stearate, Silica Hydrophobic Colloidal, Purified Water, Poultry Liver Powder, Hypromellose, Macrogol Stearate.

- **Appearance of the medicine and package contents :** The medicine is a coated tablet, round, bilaterally convex, of yellow-greyish (beige) to light brown color. The tablet is meat flavored.
- The tablets are packaged in a plastic blister pack included in a carton box.
- **Package sizes:** The medicine is provided in a carton box including plastic blister packs with 2, 4, 24 or 48 tablets.
- The number of the plastic blister packs in each carton box will vary according to the package size.
- The number of tablets included appears on the outside of the carton package.
- Not all package sizes may marketed.
- **Registration holder:** Vetmarket Ltd., 23 HaChoresh Rd., Industrial Park Modi'in District
- **Manufacturer:** Virbac, Carros, France

Registration number in the National Drug Registry of the Ministry of Health: 159.10.34768.00

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