PACKAGE LEAFLET FOR:

Levamisole 5% oral solution

LEVAMISOL 5% oral solution

Cattle, sheep, pigs, dogs and chickens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING, IF THEY ARE DIFFERENT

VETPROM AD, Radomir, Bulgaria, 26 Otets Paisiy Str.

Phone .: 0777 / 8-24-93, 8-02-68; Fax: 0777 / 8-23-91

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2. NAME OF THE VETERINARY MEDICINAL PRODUCTS

Levamisole 5% oral solution

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3. ACTIVE SUBSTANCE(S) AND EXCIPIENTS CONTENT

Contain in 100 ml:

Active substance:

Levamisole Hydrochloride 5.0 g

Excipients:

Chlorocresol

Sodium Metabisulphite

Disodium Edetate

Citric Acid Monohydrate

Sodium Citrate

Purified Water

4. THERAPEUTIC INDICATIONS

In cattle and sheep invasions with haemonchus contortus, ostertagia ostertagi, trichostrongylus, nematodirus, cooperia oncophora, esophagostomy, bunostomum phlebotomum, trichuris trichiura, dictyocaulus, geigeria, chabertia ovina, protostrongylidae.

In swine invasions with ascaris, hyostrongylus rubidus, metastrongylus apri, esophagostomy and trichuris trichiura.

In carnivorous animals invasions with toxocara and toxascaris, hookworms and uncinaria stenocephala and trichuris vulpis.

In birds invasions with acaridae, heterakis gallinarum and syngamus trachea.

5. CONTRAINDICATIONS

Do not use together with diethylcarbamazine and organophosphorus compounds.

Do not use in pregnant animals in the last third of pregnancy.

Do not use in goats, due to known sensitivity to the active substance.

6. ADVERSE REACTIONS

Temporary excitement; hypertension; salivation; diarrhea; erythema; agranulocytosis are observed in some animals after taking levamisole.

The frequency of adverse reactions is determined by the following classification:

- Very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- Common (more than 1 but less than 10 animals per 100 animals)
- Not frequent (more than 1 but less than 10 animals in 1,000 animals)
- Rare (more than 1 but less than 10 animals in 10,000 animals)
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious or other effects from the use of this veterinary medicinal product not listed in this leaflet, please inform your veterinarian.

7. TARGET SPECIES

Cattle, sheep, pigs, dogs and chickens.

8. DOSAGE FOR EACH SPECIES, AND METHOD OF ADMINISTRATION

Route of administration: oral with drinking water

dose: cattle - 0.0075 - 0,008 g/kg bw (0,15-0,16 ml 5% solution/kg body weight);
sheep and pigs - 0,0075 g/kg bw (0,15 ml 5% solution/kg body weight);
dogs - 0.01 g/kg bw (0,2 ml 5% solution/kg body weight);
chickens - 0.018 - 0.036 g / kg bw (0.4-0.7 ml 5% solution/kg body weight).

9. ADVICE ON PROPER ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Cattle, sheep, pigs and chickens: meat and offal - 3 days.

Not authorized for use in animals producing milk for human consumption.

Not authorized for use in birds producing eggs for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.

Store at temperature below 25 ° C.

Protect from light.

Store in a dry place.

Shelf-life after first opening the container: 30 days. Store in a refrigerator (2 °C – 8 °C).

12. SPECIAL WARNING(S)

Special precautions for product use in animals

Do not use in pregnant animals in the last third of pregnancy. Should not be administered with diethylcarbamazine and organophosphorus compounds.

Levamisole is contraindicated in lactating animals. In highly depleted animals or significant dysfunctions of the kidneys and liver, the product should be administered with caution.

Levamisole should be administered with caution in cattle after vaccinations, dehorning or castration (preferably to postpone intake).

Pregnancy:

Not to be administered in the last third of gestation.

Lactation:

Not to be administered during lactation.

Egg laying:

Not to be administered in birds producing eggs for human consumption.

Interaction with other veterinary medicinal products and other forms of interaction:

Should not be administered with diethylcarbamazine and organophosphorus compounds.

Overdose (symptoms, emergency procedures, antidotes), if necessary:

Overdose observed locomotor agitation, tremor, ataxia, defecation, urination, which disappear after a few minutes.

Management of overdose: Treatment is stopped and symptomatic treatment is applied.

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

VMP should not be disposed of with household waste or wastewater.

Ask your veterinarian what to do with the unnecessary VMP. These measures will help to protect the environment.

14. DATE OF REVISION OF THE TEXT

05/26/2014

15. ADDITIONAL INFORMATION

Not all package sizes may be marketed.

For any information about this product, please contact the local representative of the Marketing Authorization Holder.