

DIRONET®
spot-on

PACKAGE LEAFLET

for use of Dironet® spot-on for helminthiasis and myiasis in cats and dogs

Approved by: N.A. Vlasov, the Deputy Head of the Federal Service for Veterinary and Phytosanitary Surveillance (Development organization: NVTs Agrovetzashchita Ltd., bld. 1, 1, Kolskaia St., Moscow, 129329 Russia).

I. General

Trade name: Dironet® spot-on

Nonproprietary names of active ingredients: praziquantel, ivermectin.

Dosage form: solution for cutaneous use.

Dironet® spot-on is produced in two versions - "for dogs" and "for cats".

1 ml of the drug product depending on the modification as active ingredients contains: Dironet® spot-on for dogs - 85 mg of praziquantel and 20 mg of ivermectin, Dironet® spot-on for cats - 85 mg of praziquantel and 5 mg of ivermectin and also dimethyl sulfoxide and benzyl alcohol as excipients.

Appearance: a clear liquid from light yellow to light pink.

The shelf life of the drug product, subject to the storage conditions, is 18 years from the date of manufacture. After opening a tube-pipette the preparation cannot be stored.

It is forbidden to use the drug product after the expiration date.

Dironet® spot-on is produced in 0.2; 0.3; 0.4; 0.5; 1.0 and 2.0 ml polymer pipette tubes which are packaged in cardboard boxes containing 2, 3, 4 or 5 pcs along with package leaflet.

Store Dironet® spot-on in a sealed manufacturer's package protected from direct sunlight, separate from food and feed, at a temperature from 0°C to 30°C.

Keep out of reach of children.

Unused drug product should be disposed in accordance with legal requirements.

Available without a veterinarian's prescription.

II. Pharmacological properties

Dironet® spot-on is a combined antiparasitic drug product.

It has a wide spectrum of antiparasitic action and is active against larval and sexually mature endoparasites: nematodes, including *Toxosara canis*, *Toxosara cati*, *Toxascaris leonina*, *Ancylostoma* spp., *Uncinaria stenocephala*, *Trichinouris vulpis*, including cestodes, including *granulosus*, *Echinococcus multilocularis*, *Diphyllobothrium latum*, *Dipylidium caninum*, *Multiceps multiceps*, *Taenia* spp., *Mesocestoides lineatus*, and ectoparasites: fleas (*Ctenocephalides* spp.), lice (*Linognathus setotus*), chewing lice (*Trichodectes canis*), sarcoptoid (*Sarcoptes canis*, *Otodectes cynotis*, *Notoedres cati*) and demodectic (*Demodex canis*) ticks parasitizing in dogs and cats.

After applying the drug product to the skin, its active ingredient accumulates in the epidermis, hair follicles and sebaceous glands of the animal's body and, partially absorbed from the application area, enter the systemic circulation, organs, and tissues.

The mechanism of action of the ivermectin (which is part of the drug product) is its effect on the chlorine ion current magnitude through the membranes of the nerve and muscle cells of the parasite. The main targets are glutamate-gated chloride channels, as well as gamma-aminobutyric acid receptors. A change in the current of chlorine ions disrupts the conduction of nerve impulses, which leads to paralysis and death of nematodes and ectoparasites.

The mechanism of action of praziquantel is based on depolarization of neuromuscular ganglionic blocking agents, impaired glucose transport and microtubular function of all phases of cestode development, which causes impaired muscle innervation, paralysis, and death of parasites.

In terms of the effect upon the animal body Dironet® spot-on can be referred to moderately hazardous substances (hazard class 3 according to GOST 12.1.007-76); it does not have skin-irritating, resorptive-toxic, embryotoxic, teratogenic and sensitizing effect in recommended doses but it causes irritation in contact with mucous membranes. The drug is toxic to bees, as well as fish and other aquatic organisms.

III. Indications:

Dironet® spot-on is prescribed to dogs and cats from 2 months of age for the treatment and prevention of nematodiasis, cestodes, myiasis, otoacariasis, sarcoptic mange, notoedric mange and demodicosis.

Contraindication to the use of the drug product Dironet® spot-on is the increased individual sensitivity of the animal to the drug product ingredients. It is forbidden to use it for kittens and puppies under 2 months of age, pregnant and lactating females, animals with infectious diseases, weakened and recovering animals.

If it is necessary to use the drug in collie, bobtail and sheltie puppies and their crosses the treatment should be carried out under the supervision of the attending veterinarian due to the increased sensitivity of these breeds to ivermectin. The drug is applied to animals by spot-on application on dry intact skin. Before using a tube-pipette, break off the tip and, part the fur, apply the preparation to the animal's skin in places that are inaccessible for licking like the neck area at the base of the skull or between the shoulder blades. The solution is applied to the animal's skin at 3-4 places.

The minimum therapeutic dose of the drug product for adult animals is 0.2 ml/kg of animal weight, which corresponds to 17 mg/kg of praziquantel and 4 mg/kg of ivermectin for dogs; for cats, 17 mg/kg praziquantel and 1 mg/kg of ivermectin.

The minimum therapeutic dose of the drug product for puppies and kittens is 0.1 ml/kg of body weight, which corresponds to 8.5 mg/kg of praziquantel and 2 mg/kg of ivermectin for puppies, 8.5 mg/kg praziquantel and 0.5 mg/kg ivermectin for kittens.

A tube-pipette of the required volume or combination is selected and the drug is used in the doses indicated in the table with the consideration of the species, age and weight of the treated animal.

Animal species and weight	Drug product dose per animal, ml	Pipette tube volume/Pipette dose
Dironet® spot-on for dogs		
Puppies from 2 months of age		
up to 2 kg	0.2 (5 drops)	0.2 ml/1 pipette 0.5 ml/½ pipette
from 2 kg to 5 kg	0.5	0.5 ml/1 pipette
more than 5 kg	1.0	0.5 ml/2 pipettes
Adult dogs		
from 2 kg to 5 kg	1.0	1.0 ml/1 pipette
from 5 kg to 10 kg	2.0	1.0 ml/2 pipettes
from 10 kg to 20 kg	4.0	1.0 ml/4 pipettes
from 20 kg to 30 kg*	6.0	1.0 ml/6 pipettes 2.0 ml/3 pipettes
Dironet® spot-on for cats		
Kittens from 2 months of age		
up to 1 kg	0.1 (3 drops)	0.2 ml/ ½ pipette 0.5 ml/⅓ pipette
more than 1 kg	0.2 (5 drops)	0.2 ml/1 pipette 0.5 ml/½ pipette
Adult cats		
up to 5 kg*	1.0	1.0 ml/1 pipette

* Dironet® spot-on for dogs or Dironet® spot-on for cats are used, respectively, at a dose of 0.2 ml/kg of animal weight using combinations of various packaging pipettes for treating dogs weighing more than 30 kg or cats weighing more than 5 kg.

Do not apply the drug product to wet or damaged skin. Do not wash and bathe the animal within 4 days after treatment.

Apply the drug product once a month during the entire season of insect activity to eliminate fleas, lice and chewing lice and to prevent re-invasion.

In order to prevent re-infestation by fleas, the bedding are replaced or treated with an insecticidal agent in accordance with the instructions for its use.

The drug is applied to the skin once for the otoacariasis (ear mange) treatment. It is recommended to clean the ear canal from exudate and scabs in the course of treatment, and prescribe antimicrobial and anti-inflammatory drugs in case of otitis complication. If necessary, the treatment is repeated after 1 month.

For treatment sarcoptic mange and demodicosis in dogs, notoedrosis in cats, the drug is used 2-4 times, with an interval of 10-14 days in order to prevent possible invasion - once a month.

Treatment should to be carried out with the use of etiotropic, pathogenetic and symptomatic drugs in accordance with the instructions for their use.

For deworming of animals against round (nematodosis) and tape (cestodosis) worms of the gastrointestinal tract, a single dose of drug product is applied. A single dose of drug product is applied once a quarter for prophylactic purposes. In case of an overdose of the drug, the animal may experience weakness, tremor, excessive salivation. There are no specific means of detoxification; general measures are used to egest the drug from the body. The side effects of the drug product action during its first use and withdrawal were not observed.

It is prohibited to use Dironet® spot-on for pregnant and lactating females, as well as kittens and puppies under 2 months of age.

Violations of the drug use regimen should be avoided, as it can lead to a decrease in efficacy. If the following treatment is missed, it should be carried out as soon as possible in the same dose. As a rule side effects and complications are not observed if the drug product Dironet® spot-on is used in accordance with this package leaflet. In case of increased sensitivity and the allergic reactions, the drug should be washed off with water and detergent and, if necessary, antihistamines and symptomatic therapy should be prescribed to the animal.

Dironet® spot-on should not be used concurrently with other antiparasitic drugs.

Dironet® spot-on is not intended for use in productive animals.

IV. Personal preventive measures

The requirements set to personal hygiene and labor safety and health regulations imposed on handling drug products must be complied with while Dironet® spot-on.

It is prohibited to smoke, drink or eat while working with the drug product. After handling the drug product wash your hands with soap and lukewarm water. Do not touch the areas of drug product application and do not let the animal to get close to small children within 48 hours after treatment with Dironet® spot-on.

It is prohibited to use empty package where the drug product has been contained for household purposes – the packages must be disposed of with solid waste. People with hypersensitivity to the ingredients of the drug product must avoid direct contacting with Dironet® spot-on. At incidental contact of the drug product with skin or eye mucosa rinse thoroughly with plenty of water. In the event of occurrence of allergic reactions or at incidental swallowing of the drug product consult the physician immediately (take away with you this package leaflet or the drug product label).

Marketing Authorisation No.: in Russia 77-3-14.16-3500 No. IIBP-3-3.7/01973 dated 02.12.2016

/AVZ

animal health/

Name and address of the production site of the manufacturer of the drug product for veterinary use:

AVZ S-P LTD., 1, Tsentralnaia str., Sergiyev Posad, Moscow region, 141305 Russia.

Name and address of the organization authorized by the marketing authorization holder or owner of the drug product to accept claims from the consumers: AVZ S-P LTD., 1, Tsentralnaia str., Sergiyev Posad, Moscow region, 141305 Russia.

24-hour hotline: 8-800-700-19-93 (toll free in Russia).

See information on product conformity assessment at: www.vetmag.ru.