IMMITICIDE

Freeze dried powder for injection into dogs

Composition: Melarsomine dihydrochloride 50mg, water for injection 2ml.

Product Description: White lyophilic powder.

Pharmacodynamics: Melarsomine is a derivative of arsenic in macrofilaricidal activity. Its specific mode of action is unknown.

Pharmacokinetics: In dogs after intramuscular administration, absorption is very fast. It is fully bioavailable. The maximum plasma concentration (Cmax) of arsenic (0.59 mg / ml) was obtained 10.7 minutes after

The half-life in plasma was estimated at 3.87 minutes.

In dogs: Treatment of heartworm disease (sub-clinical and/or moderate) due to Dirofilaria immitis.

Routes of administration: Deep intramuscular injection.

Dosage:

Melarsomine 2.14 mg per kg body weight (i.e. 1 ml/10 kg of reconstituted solution) twice at 24 hours apart.

One vial of solvent is added to the vial of freeze-dried to form reconstituted solution.

Inject by intramuscular (with a new needle which has not been used for reconstitution) in the lumbar

muscles. Change sides for the second dose the next day.

To avoid any risk of overdose, well weigh the animal and accurately measure the volume of the solution to be injected.

 $Do \ not \ give \ in \ very \ severe \ heartworm \ disease \ (vena \ cava \ syndrome, \ spontaneous \ pneumothorax). \ In \ these$ cases, treatment must be first surgery.

Warnings and Precautions:

Special precautions for use

i) Special precautions for use in animals Ensure proper restraint of the animal during injection. Transient edema appears when injected subcutaneously or intermuscularly fascia. Rest the dog more or less strictly depending on the severity of heartworm disease after administration to reduce the risk of thromboembolism associated with the destruction of worms after treatments for dogs with heartworm disease.

ii) Other precautions

Particular precautions to be taken by the person administering the product to animals

This product is irritating. Wash hands after use, avoid contact with eyes. In case of contact with eyes, rinse the eye with running water for several minutes. If in doubt or in case of accidental ingestion, seek medical

Special precautions for the disposal of unused veterinary medicinal product or waste materials

derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Interactions with other medicaments: No known interaction.

Statement on usage during pregnancy and lactation: In the absence of specific data, do not use in pregnant bitches

Adverse Effects:

Occasionally a dog may show reaction of pain at the injection site accompanied by edema, which may cause temporary locomotion discomfort. These signs usually disappear within a few days or even two to

General reaction:

Gastrointestinal symptoms such as vomiting, diarrhea and salivation may occur.

Transient anorexia one or two days is common.

Some animals may be agitated with or without salivation and tremors a few minutes after the injection, but transiently.

At the end of the first week after the injections, there may be symptoms of fever, anorexia and depression, which seem to reflect an allergic reaction in the lungs to foreign matter arising from the death of the worms. Treatment with corticosteroid is very useful.

Seven to twenty days after the treatment a thromboembolism syndrome associated with the allergic reaction resulted in fatigue, depression, anorexia, and (or) tachypnea, dyspnea, can be observed. The dogs should receive a specific treatment (eg, with acetylsalicylic acid) and monitoring (strict rest).

Overdose and Treatment: In case of overdose in animals and at the onset of signs of intoxication (nervous disorders, vomiting, diarrhea etc), dimercaprol can be administered at a dose of 4 mg / kg intramuscularly.

Storage Conditions: Store away from heat. Store below 25°C. The 2.5% solution can be used up to 24 hours after reconstitution if stored at $2 - 8^{\circ}$ C and away from light. Do not re-use the water of injection supplied.

Withdrawal Period: Not applicable.

Packing: Box with 5 vials of 50mg lyophilisate and 5 vials of 2ml solvent.

FOR VETERINARY USE ONLY

Registration holder and repacker:



RHONE MA MALAYSIA SDN BHD (200001023279)

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Manufactured by:

BOEHRINGER INGELHEIM ANIMAL HEALTH FRANCE

4 Chemin du Calquet, 31000 Toulouse, France

Date of revision of package insert: June 2020

5LIMMIT3-005 03/XXX



LABEL CODE:	VERSION	COLORS
5LIMMIT3-005		Black
PRODUCT: IMMITICIDE FREEZE DRIED POWDER FOR INJECTION 50MG	Version: 3	
PACK SIZE: 5 VIALS FREEZE DRIED POWDER FOR INJECTION AND 5 VIALS WATER FOR INJECTION	MMM/YY:	
COUNTRY: MY		
DIMENSIONS: $cm = 10 \times 14$		Please use the official PANTONE® (P) matching system for an accurate color representation.

Marketing approval:	Regulatory approval:	GMP approval:
COMPLETE	COMPLETE	COMPLETE
NAME:	NAME:	NAME:
DATE +	DATE +	DATE +
SIGNATURE:	SIGNATURE:	SIGNATURE: