

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:

Vetmedin 1.25 mg Veterinary
Vetmedin 5 mg Veterinary
Vetmedin 10 mg Veterinary
Chewable tablets for dogs

2) Name and quantity of active ingredient in a dosage unit:

Medicine name	Amount of active ingredient in each chewable tablet
Vetmedin 1.25 mg Veterinary	1.25 mg pimobendan
Vetmedin 5 mg Veterinary	5 mg pimobendan
Vetmedin 10 mg Veterinary	10 mg pimobendan

For a list of 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 dogs:

- to treat heart failure originating from ventricular dilation and cardiomyopathy or valvular insufficiency.
- to treat Doberman Pinschers following ventricular dilation and cardiomyopathy that has been diagnosed by ultrasound, before the appearance of clinical signs of disease.
- to treat thickening of the mitral valve (the leaflets between the heart's atria and ventricles), before the appearance of clinical signs of disease, to delay onset of heart failure.

Therapeutic group: This medicine belongs to a class of cardiac stimulants (excluding cardiac glycosides) that function as phosphodiesterase III inhibitors.

4) Contraindications:

Do not use this medicine:

- if your dog is sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine. The active ingredient is listed in section 2, and the other ingredients are listed in section 13.
- if your dog has thickening of his heart muscle (hypertrophic cardiomyopathy).
- in case of disease where an improvement in cardiac output cannot be achieved for functional or anatomical reasons (e.g. aortic stenosis).
- if your dog has liver function problems.

5) Side effects:

As with any medicine, using this medicine may cause side effects in some dogs. Do not be alarmed by this list of side effects; your dog may not experience any of them.

Rare side effects (occur in 1–10 in 10,000 dogs): vomiting (dose dependent and can be prevented by the veterinarian reducing the dose) diarrhoea, anorexia, apathy/lethargy, increased heart rate (positive chronotropic effect) – transient side effects. With chronic administration of this medicine, there was impaired closure of the left valve between the atrium and the ventricle (the mitral valve) in the heart.

Very rare side effects (occur in less than 1 in 10,000 dogs): impaired blood clotting (visible as very small bleeds under the skin and in mucous membranes). This effect disappears when treatment is withdrawn.

If any side effect gets worse, or if your dog 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 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

6) Target animals:

This medicine is intended for dogs only.

7) Route of administration and dosage in animals:

Always use 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 to take this medicine.

Do not exceed the recommended dose.

Do not exchange Vetmedin Veterinary products with another medicine containing the active ingredient pimobendan, unless the veterinarian has been notified and approves.

Dosage form: chewable tablets.

Dosage: To ensure an accurate dosage, weigh the dog accurately before starting treatment. The daily dose is calculated according to 0.2–0.6 mg pimobendan per kg dog body weight. Divide the daily dose in two – half a daily dose in the morning and the other half 12 hours later.

The preferred daily dose is 0.5 mg pimobendan per kg dog body weight. Divide the daily dose in two – half a daily dose in the morning and the other half 12 hours later.

A veterinarian should adjust the individual dog's regular dose according to disease severity.

Vetmedin 1.25 mg Veterinary: One tablet in the morning and one tablet in the evening is the correct amount for a dog weighing 5 kg.

Vetmedin 5 mg Veterinary: One tablet in the morning and one tablet in the evening is the correct amount for a dog weighing 20 kg.

Vetmedin 10 mg Veterinary: One tablet in the morning and one tablet in the evening is the correct amount for a dog weighing 40 kg.

Dosage for dogs of other weights can be prepared by combining several chewable tablets of suitable strengths.

To allow best dosing according to body weight, the tablets can be halved to form half-doses.

Administration schedule: one tablet in the morning and one tablet in the evening, as directed by the veterinarian.

Do not give this medicine in the dark! Check the label and dose every time give your dog this medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your veterinarian or pharmacist.

8) How to use this medicine:

- These chewable tablets are palatable to most dogs.
- Give this medicine on an empty stomach, at least one hour before feeding, since absorption is reduced when it is given with food.
- To allow best dosing according to body weight, the tablets can be halved to form half-doses.
- Halve tablets by breaking along the score line marked on both sides of the tablet.
- Treatment with this medicine may be combined with a diuretic, e.g. furosemide.

9) Withdrawal period:

Withdrawal before sacrifice: Not applicable. This medicine is intended for dogs only.

10) Warnings:

Special warnings about the safety of using this medicine in animals: Blood glucose should be tested in dogs with existing diabetes mellitus. Your veterinarian may decide to order heart imaging tests before starting treatment.

Dogs treated with this medicine should have their heart function tested and monitored as directed by their veterinarian.

The active ingredient in this medicine is broken down in the liver. Be cautious when giving this medicine to dogs with severe liver failure.

These tablets contain flavouring. In order to avoid accidental ingestion, store them out of reach of animals.

Special safety precautions for the person handling the medicine: To avoid accidental ingestion of the medicine by a child, divided or unused tablets should be returned to the open blister pocket and placed back in the cardboard box. Wash hands after use.

If a person has accidentally taken an overdose, particularly if this is a child, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Accidental ingestion by people may cause tachycardia, orthostatic hypotension, flushing of the face, and headache.

Pregnancy and lactation: The safety of this medicine has not been established during pregnancy and lactation in bitches. In these cases, use only according to the benefit-risk assessment by the responsible veterinarian.

Laboratory studies in rats and rabbits have not produced evidence of harmful or dangerous (teratogenic or foetotoxic) effects on the foetus. However, these studies have shown evidence of dangerous effects at high doses on the pregnant bitch and the foetus. The medicine is excreted into the bitches' milk.

Drug interactions and other interactions: If your dog is getting or has recently had other medicines and medicinal products (including heart and blood pressure medicines), tell your veterinarian or pharmacist. Particularly inform your veterinarian or pharmacist if your dog is getting: the calcium antagonists verapamil and diltiazem, the β -antagonist propranolol. Concomitant use of these medicines can weaken the activity of Vetmedin Veterinary.

Overdose: An overdose of this medicine may cause increased heart rate, vomiting, loss of muscle control, heart murmurs or lower blood pressure. In this situation, the dosage should be reduced and appropriate symptomatic treatment should be initiated.

• In prolonged administration (6 months) to healthy beagle dogs at 3 and 5 times the recommended dose, mitral valve thickening and left ventricular hypertrophy were observed. These changes are caused by this medicine's activity.

• **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 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.

• **Shelf life of a divided (halved) tablet:** After dividing the tablet, the remaining half can be kept for 3 days, if returned to its original blister pocket and placed back in the cardboard box.

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

• Do not throw away medicines in the toilet or in household waste.

• Ask your pharmacist or veterinarian how to dispose of expired or unused medicines. These measures will help protect the environment.

13) Additional information:

• **In addition to the active ingredients, this medicine also contains the following inactive ingredients:**

Lactose Monohydrate, Liver Powder Flavour, Microcrystalline Cellulose, Starch Pregelatinized, Sodium Starch Glycolate (Type A), Dried Yeast, Macrogol 6000, Talc, Stearoyl Macroglyglycerides, Magnesium Stearate.

• **What the medicine looks like and contents of the pack:** This medicine is an oval, brown tablet with a score line on both sides that can be used to divide the tablet in two equal halves.

• The tablets are packaged in blister strips packed in cardboard boxes.

• **Pack size:** This medicine is supplied in a cardboard box with blister strips of 20, 50, or 100 chewable tablets.

• The number of blister strips in each box varies by pack size.

• The number of tablets in the pack is listed on the box.

• Not all packs sizes may be marketed.

• **Registration holder:** Beit Erez Havat Milatim Ltd., P.O.B. 209, Mishmar Hashiva 50297.

• **Manufacturer:** Boehringer Ingelheim Vetmedica GmbH, Ingelheim am Rhein, Germany.

This medicine is intended for male and female dogs.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Vetmedin 1.25 mg Veterinary: 180-54-36494-99
Vetmedin 5 mg Veterinary: 180-55-36495-99
Vetmedin 10 mg Veterinary: 180-56-36496-99

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