

Consumer Leaflet for a Veterinary Product

This medicine is marketed according to a veterinarian's prescription only.

For animal use only

1. Name of the veterinary medicine, form and strength

Tablets.

CARDISURE FLAVOURED VETERINARY 1.25 MG

CARDISURE FLAVOURED VETERINARY 2.5 MG

CARDISURE FLAVOURED VETERINARY 5 MG

CARDISURE FLAVOURED VETERINARY 10 MG

2. Active ingredient and its quantity in a single dose:

Each tablet of Cardisue 1.25 contains Pimobendan 1.25 mg.

Each tablet of Cardisue 2.5 contains Pimobendan 2.5 mg.

Each tablet of Cardisue 5 contains Pimobendan 5 mg.

Each tablet of Cardisue 10 contains Pimobendan 10 mg.

For the list of excipients, see section 13.

3. What is the medicine intended for

For the treatment of canine congestive heart failure originating from valvular insufficiency (mitral and/or tricuspid regurgitation) or dilated cardiomyopathy.

Therapeutic group: cardiac stimulant (phosphodiesterase inhibitor).

4. Contra-indications

Do not use in cases of hypertrophic cardiomyopathies or clinical conditions where an augmentation of cardiac output is not possible for functional or anatomical reasons (e.g. aortic stenosis).

Do not use in cases of hypersensitivity to the active ingredient or to any of the excipients.

5. Side effects

- Rare side effects (more than 1 but less than 10 animals in 10,000 animals)

A positive chronotropic effect (an increase in heart rate) and vomiting may occur in rare cases. However, these effects are dose-dependent and may be avoided by reducing the dose in these cases.

In rare cases transient diarrhoea, anorexia or lethargy have been observed.

In rare cases, a mitral valve regurgitation has been observed during chronic pimobendan treatment in dogs with mitral valve disease.

- Very rare side effects (less than 1 animal in 10,000 animals, including isolated reports)
Although a relationship with pimobendan has not been clearly established, in very rare cases, signs of effects on primary haemostasis (petechiae on mucous membranes, subcutaneous haemorrhages) may be observed during treatment .
These signs disappear when the treatment is withdrawn .

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

Dogs.

7. Dosage and administration

Do not exceed the recommended dosage.

Determine the body weight accurately before treatment to ensure correct dosage.

The usual dose is: the tablets should be administered orally at a dose range of 0.2 mg to 0.6 mg pimobendan/kg body weight per day. The preferable daily dose is 0.5 mg pimobendan/kg body weight. The dose should be divided into two administrations (0.25 mg/kg body weight each), one half of the dose in the morning and the other half 12 hours later. The maintenance dose should be individually adjusted by the responsible veterinarian according to the severity of the disease.

Since this absorption is considerably reduced when the product is administered with food, treat animals at least 1 hour before feeding.

The product may be combined with a diuretic treatment, e.g. furosemide.

To break a tablet into two halves, place the tablet on an even surface with the scored side up, hold one half of the tablet and press down on the other half.

8. How to use the product

Dosage of 1.25 mg:

To break a tablet into two halves, place the tablet on an even surface with the scored side up, hold one half of the tablet and press down on the other half.



Dosage of 2.5mg, 5mg, 10mg:

To break the tablet into quarters, place the tablet on an even surface with the scored side up and apply pressure on the middle with your thumb.



9) **Withdrawal period**- Not applicable

10) **Warnings**

- **Special warning for use in the target species:**

- The product is flavoured, therefore should be stored at a safe place out of reach of the dog.
- An in vitro study in rat tissue demonstrated that Pimobendan increased glucose-induced insulin release from pancreatic β -cells in a dose-dependent manner. If the product is administered to diabetic dogs, blood glucose levels should be carefully monitored.
- As pimobendan is metabolised in the liver, particular care should be taken when administering the product to dogs with severe hepatic insufficiency.
- Monitoring of cardiac function and morphology is recommended in animals treated with pimobendan.
- Do not use the drug in dogs that have a strong murmur above the left base of the heart (the front and upper left chest area), before the animal has undergone a comprehensive cardiology examination that also includes spectral echo Doppler imaging.

- **Special precautions regarding safety of persons treating with the medicine:**

- Wash hands after use.
- In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
- **Pregnancy and lactation:** Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or foetotoxic effects. However, these studies have shown evidence of maternotoxic and embryotoxic effects at high doses, and have also shown that pimobendan is excreted into milk. The safety of the product has not been assessed in pregnant or nursing bitches. Use only according to the benefit/risk assessment by the responsible veterinarian.
- **Overdose:** symptoms of increase in heart rate effect and vomiting may occur. Mitral valve thickening and left ventricular hypertrophy were observed in some dogs.
- **Interactions with other medicines and other types of interactions:** The pimobendan-induced increase in contractility of the heart is attenuated in the presence of the calcium antagonist verapamil and the β -antagonist propranolol.

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.
- Shelf life after opening: Return any divided tablet to the opened blister and use within 3 days.
- **Storage conditions:** below 25°C.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of as toxic waste. Do not throw into sewage.

13) Additional information:

- In addition to the active substance, the medicine also contains:
Cellulose, microcrystalline, Natural meat flavor, Croscarmellose sodium, Magnesium stearate.
- Appearance of the medicine and package contents:
Cardisure 1.25mg: A light brown round tablet, scored, diameter 9 mm.
Cardisure 2.5mg - A light brown round tablet, quadrisept, diameter 12 mm.
Cardisure 5mg - A light brown round tablet, quadrisept, diameter 15 mm.
Cardisure 10mg - A light brown round tablet, quadrisept, diameter 20 mm.
- Package sizes: A carton box, containing trays of 10 tablets each, each box containing 20, 50, 100 or 250 tablets. Not all package sizes may be marketed.
- **Manufacturer:** Eurovet Animal Health BV, Handelsweg 25, 5531 AE Bladel, The Netherlands
- **Registration holder:** Vetmarket Ltd., 23 HaChoresh Rd., Industrial Park Modi'in District 7319900

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

CARDISURE FLAVOURED VETERINARY 1.25 MG: 167-15-35652

CARDISURE FLAVOURED VETERINARY 2.5 MG 167-16-35653

CARDISURE FLAVOURED VETERINARY 5 MG 167-17-35654

CARDISURE FLAVOURED VETERINARY 10 MG 167-18-35655

Approved on April 2021