1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pimocard 1.25 mg flavoured tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:
Pimobendan 1.25 mg

Excipients:

Qualitative composition of excipients and other constituents
Cellulose, microcrystalline (E460)
Croscarmellose sodium
Magnesium stearate
Natural meat flavour

Light brown round tablets, scored on one side and plain on the other side.
The tablets can be divided into 2 equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in cases of hypertrophic cardiomyopathies or diseases in which an improvement in cardiac output cannot be achieved for functional or anatomical reasons (e.g. aortic stenosis).
Since pimobendan is metabolised mainly via the liver, do not use in dogs with severe impairment of liver function.
See also section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Blood glucose should be tested regularly during treatment in dogs with existing diabetes mellitus.

Monitoring of cardiac function and morphology is recommended in animals treated with pimobendan. See also section 3.6.

The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

To the physician: accidental ingestion, especially by a child, may lead to the occurrence of tachycardia, orthostatic hypotension, flushing of the face and headaches.

This veterinary medicinal product may cause cardiovascular effects in the event of accidental ingestion.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	Increased heart rate[1,2], Increase in mitral valve regurgitation[3] Vomiting[2], Diarrhoea[4] Anorexia[4], Lethargy[4]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Mucosa petechiae[5], Haemorrhages (subcutaneous)[5]

[1] Due to a slight positively chronotropic effect.
[2] These effects are dose-dependent and can be avoided by reducing the dose.
[3] Observed during chronic pimobendan treatment in dogs with mitral valve disease.
[4] Transient.
[5] A relationship with pimobendan has not been clearly established, signs disappear when the treatment is withdrawn.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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 veterinary medicinal product has not been assessed in pregnant or nursing bitches. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

In pharmacological studies no interaction between the cardiac glycoside ouabain and pimobendan was detected. The pimobendan-induced increase in contractility of the heart is attenuated in the presence of the calcium antagonist verapamil and diltiazem and the β-antagonist propranolol.

3.9 Administration routes and dosage

Oral use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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 approximately 12 hours later. Each dose should be given approximately one hour before feeding.

Do not exceed the recommended dosage.

The veterinary medicinal product may be combined with a diuretic treatment such as furosemide.

To break a single scored 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.



3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

An overdose may cause vomiting, a positive chronotropic effect, apathy, ataxia, heart murmurs or hypotension. In this situation, the dosage should be reduced and appropriate symptomatic treatment should be initiated.

In prolonged exposure (6 months) of healthy beagle dogs at 3 and 5 times the recommended dose, mitral valve thickening and left ventricular hypertrophy were observed in some dogs. These changes are of pharmacodynamic origin.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QC01CE90.

4.2 Pharmacodynamics

Pimobendan, a benzimidazole-pyridazinone derivative, is a non-sympathomimetic, non-glycoside inotropic substance with potent vasodilatative properties.

Pimobendan exerts its stimulatory myocardial effect by a dual mode of action: it increases calcium sensitivity of cardiac myofilaments and inhibits phosphodiesterase (type III). It also exhibits a vasodilatory action through inhibition of phosphodiesterase III activity.

When used in cases of symptomatic valvular insufficiency in conjunction with furosemide, the veterinary medicinal product has been shown to improve the quality of life and extend life expectancy in treated dogs.

When used in a limited number of cases of symptomatic dilated cardiomyopathy in conjunction with furosemide, enalapril and digoxin, the veterinary medicinal product has been shown to improve the quality of life and to extend life expectancy in treated dogs.

4.3 Pharmacokinetics

Absorption
Following oral administration of this veterinary medicinal product the absolute bio-availability of the active principle is 60-63%. Since this bio-availability is considerably reduced when pimobendan is administered with food or shortly thereafter, it is recommended to treat animals approximately 1 hour before feeding.

Distribution
The volume of distribution is 2.6 l/kg, indicating that pimobendan is distributed readily into the tissues. The mean plasma protein binding is 93%.

Metabolism
The compound is oxidatively demethylated to its major active metabolite (UD-CG 212). Further metabolic pathways are phase II conjugates of UD-CG-212, in essence glucuronides and sulphates.

Elimination
The plasma elimination half-life of pimobendan is 1.1 ± 0.7 hours.
The main active metabolite is eliminated with a plasma elimination half-life of 1.5 ± 0.2 hours. Almost the entire dose is eliminated via the faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life of divided tablets after first opening the blister: 3 days.

5.3 Special precautions for storage

Do not store above 30 °C.

Return any divided tablet to the opened blister and use within 3 days.

5.4 Nature and composition of immediate packaging

Aluminium-PVC/PE/PVDC blister:
10 tablets per blister: 2, 5, 10 or 25 blisters per carton.

Aluminium-aluminium blister:
10 tablets per blister: 2, 5, 10 or 25 blisters per carton.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10989/067/001

8. DATE OF FIRST AUTHORISATION

22/01/2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

20/05/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).