1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pimotab 1.25 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substances:

Pimobendan 1.25 mg

Excipients:

Qualitative composition of excipients and other constituents
Citric acid, anhydrous
Povidone K 25
Lactose monohydrate
Cellulose, microcrystalline
Croscarmellose sodium
Chicken flavour
Yeast (dried)
Silica, colloidal hydrated
Magnesium stearate

Light brown with brown spots, round and convex tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 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 dilated cardiomyopathy or valvular insufficiency (mitral and/or tricuspid valve regurgitation).
(See also section 3.9).

3.3 Contraindications

Do not use pimobendan in hypertrophic cardiomyopathies or in diseases in which an improvement in cardiac output cannot be achieved for functional or anatomical reasons (e.g. aortic stenosis).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The blood glucose should be tested regularly during treatment in dogs with existing diabetes mellitus.

Since pimobendan is metabolised mainly via the liver, it should not be used in dogs with severe impairment of liver function.

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

The chewable 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:
This veterinary medicinal product may cause tachycardia, orthostatic hypotension, flushing of the face and headaches.
To avoid accidental ingestion, especially by a child, unused tablet parts should be placed back into the blister and carton and carefully kept away from children. Part-used tablets should be used at the time of the next dose.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

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

[1] These signs are dose-dependent and can be avoided by reducing the dose.
[2] Transient
[3] Due to a slight positively chronotropic effect.
[4] Observed during chronic pimobendan treatment in dogs with mitral valve disease.
[5] A relationship with pimobendan has not been clearly established. These 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:
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. The safety of the veterinary medicinal product has not been assessed in pregnant bitches.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Lactation:

Laboratory studies in rats have also shown that pimobendan is excreted into milk.
The safety of the veterinary medicinal product has not been assessed in 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 strophanthin and pimobendan was observed. The pimobendan-induced increase in cardiac contractility is attenuated by calcium antagonists and by β-antagonists.

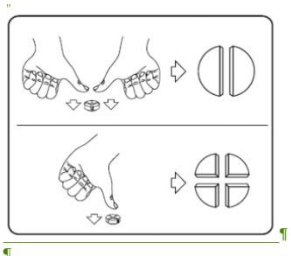
3.9 Administration routes and dosage

Oral use.
Do not exceed the recommended dosage.
To ensure a correct dosage, body weight should be determined as accurately as possible.The dose should be orally administered and within the dose range of 0.2 mg to 0.6 mg pimobendan/kg bodyweight, divided into two daily doses. The preferable daily dose is 0.5 mg/kg bodyweight, divided into two daily doses (0.25 mg/kg bodyweight each). Each dose should be given approximately 1 hour before feeding.

This corresponds to:
One 1.25 mg chewable tablet in the morning and one 1.25 mg chewable tablet in the evening for a body weight of 5 kg.

Chewable tablets can be divided into four equal parts, for dosage accuracy, according to the bodyweight.

Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.
To split into 2 equal parts:
Press your thumbs down on both sides of the tablet.
To split into 4 equal parts:
Press your thumb down in the middle of the tablet.



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

In case of congestive heart failure a life-long treatment is recommended. The maintenance dose should be individually adjusted according to the severity of the disease.

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

In the case of overdose, a positive chronotropic effect, vomiting, apathy, ataxia, heart murmurs or hypotension may occur. 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

When used in cases of symptomatic valvular insufficiency in conjunction with furosemide the 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.

Pimobendan, a benzimadazole-pyridazinone derivative has a positive inotropic action and possesses pronounced vasodilator properties.

The positive inotropic effect of pimobendan is mediated by two mechanisms of action: increase in calcium sensitivity of cardiac myofilaments and inhibition of phosphodiesterase III. Thus, the positive inotropism is triggered neither by an action similar to that of the cardiac glycosides nor sympathomimetics.
The vasodilator effect arises from inhibition of phosphodiesterase III.

4.3 Pharmacokinetics

Following oral administration of the veterinary medicinal product the absolute bio-availability of the active principle is 60 - 63%. The bio-availability is considerably reduced when pimobendan is administered with food or shortly thereafter. After oral administration of a single dose of 0.2 - 0.4 mg/kg pimobendan to dogs fasted overnight, the plasma concentrations increased fast. The peak concentration (C_{max}) of ~ 24 ng/mL was reached after a median of 0.75 hours (T_{max} ranged from 0.25 to 2.5 hours).

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%.

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.

The plasma elimination half-life of pimobendan is ~ 1 hour. Almost the entire dose is eliminated in 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: 5 years
Shelf life of divided tablets after first opening the immediate packaging: 3 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Aluminium-OPA/Aluminium/PVC blisters containing 10 tablets.
Cardboard box of 30, 50 or 100 tablets.

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

CP- Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10810/018/001

8. DATE OF FIRST AUTHORISATION

17/07/2020

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

26/11/2025

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).