/1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROBENDAN 1.25 mg, chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Pimobendan ……..1.25 mg

Excipients:

Qualitative composition of excipients and other constituents
Cellulose microcrystalline
Carmellose sodium
Pork liver powder
Glycerol dibehenate
Croscarmellose sodium
Magnesium stearate

Square brownish tablet with two break marks divisible into two or four equal parts.

3. CLINICAL INFORMATION

3.1. Target species

Dogs.

3.2. Indications for use for each target species

The product is indicated for the treatment of canine congestive heart failure originating from dilated cardiomyopathy or valvular insufficiency (mitral and/or tricuspid valve regurgitation).

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).
Since pimobendan is metabolised mainly via the liver, it should not be used 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:

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

Use with caution in epileptic dogs.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

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

People with known hypersensitivity to pimobendan or to any of the excipients should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.
Advice to doctors: accidental ingestion, especially by a child, may lead to the occurrence of tachycardia, orthostatic hypotension, flushing of the face and headaches.

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[a,b]; Vomiting[b], Diarrhoea[c]; Anorexia[c], Lethargy[c]; Heart valve disorder[d].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Mucosa petechiae[e], Skin (subcutaneous) haemorrhage[e].

[a] slight positively chronotropic effect.
[b] these effects are dose-dependent and can be avoided by reducing the dose.
[c] transient.
[d] an increase in mitral valve regurgitation has been observed during chronic pimobendan treatment in dogs with mitral valve disease.
[e] these signs of effects on primary haemostasis 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 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 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 strophanthin and pimobendan was observed.
The pimobendan-induced increase in cardiac contractility is attenuated by the calcium antagonists verapamil and diltiazem and by the β-antagonist propranolol.

3.9. Administration routes and dosage

Do not exceed the recommended dosage.
Determine the bodyweight accurately before treatment to ensure correct dosage.
The product must be administered orally within the dosage range of 0.2 mg to 0.6 mg pimobendan/kg bodyweight per day. The preferable daily dose is 0.5 mg/kg b.w., divided into two daily administrations (each 0.25 mg/kg b.w.): a half dose in the morning and the other half dose about 12 hours later.

Each dose must be administered approximately 1 hour before feeding.
To allow accurate dosing according to body weight, the chewable tablet can be divided along the designated score line.

For correct administration, the following dosage scheme is recommended:

Approximate dose to be repeated morning and evening 12h apart, corresponding to approximately 0.25 mg of pimobendan/kg b.w.				
Weight of the animal (kg)	**1**	**2**	**4**	**5**
1.25 mg FATROBENDAN Tablets	¼	½	¾	1

The product may be combined with a diuretic treatment (e.g. furosemide).
Return any divided tablets to the blister pack and use within 3 days. Divided tablets should be used at the next administration. Any divided tablets remaining after the last administration of the product should be discarded.

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

Pimobendan, a benzimadazole-pyridazinone derivative has a positively inotropic action and possesses pronounced vasodilator properties.
The positive inotropic effect of pimobendan is mediated by two action mechanisms: 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 sympathomimetically.
The vasodilator effect arises from inhibition of phosphodiesterase III.
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.

4.3. Pharmacokinetics

Absorption:
Following oral administration of pimobendan, the absolute bioavailability of the active substance is 60-63%. As this bioavailability is considerably reduced by concomitant consumption of food or by administration of the medicinal product immediately after meals, it is advisable to administer the medicinal product one hour before feeding.

Distribution:
The volume of distribution is 2.6 l/kg, and indicates that pimobendan is distributed immediately into the tissues. The binding to plasma proteins is, on average, 93%.

Metabolism:
Pimobendan is subjected to a process of oxidative demethylation which leads to the formation of its principal active metabolite (UD-CG 212). Further metabolic pathways are formed by the phase II conjugation of UD-CG 212, mainly to glucuronides and sulphates.

Elimination:
The plasma elimination half-life of pimobendan is 0.4 ± 0.1 h, consistent with a high clearance rate (90 ± 19 ml/min/kg) and a short mean residence time (0.5 ± 0.1 h).
The principal active metabolite has a plasma elimination half-life of 2.0 ± 0.3 h. Almost the entire dose administered 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: 3 years
Return any divided tablets to the blister pack and use within 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

PVC/PE/PVdC/PE/PVC blister sealed with thermoheated aluminium foil containing 10 tablets.

Package-sizes:
- Cardboard box with 1 blister of 10 tablets (10 tablets)
- Cardboard box with 5 blisters of 10 tablets (50 tablets)
- Cardboard box with 10 blisters of 10 tablets (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

FATRO S.p.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10836/011/001

8. DATE OF FIRST AUTHORISATION

19 March 2021

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

01/12/2023

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).