ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box: 10 tablets
50 tablets
100 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fatrobendan 5 mg, chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains pimobendan 5 mg.

3. PACKAGE SIZE

10 tablets
50 tablets
100 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Return any divided tablets to the blister pack.
Divided tablets should be used at the next administration.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: FATRO S.p.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 11557/3004

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fatrobendan

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

pimobendan 5 mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fatrobendan 1.25 mg, chewable tablets for dogs
Fatrobendan 5 mg, chewable tablets for dogs
Fatrobendan 10 mg, chewable tablets for dogs

2. Composition

Each tablet contains:

Fatrobendan 1.25 mg:
Active substance: pimobendan 1.25 mg

Fatrobendan 5 mg:
Active substance: pimobendan 5 mg

Fatrobendan 10 mg:
Active substance: pimobendan 10 mg

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

3. Target species

Dogs.

4. Indications for use

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

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
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 “Special warnings”).

6. Special warnings

Special warnings:
None.

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 “Adverse events”). 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.
To avoid accidental ingestion, especially by a child, unused tablet parts should be placed back into the blister and carton and carefully kept 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.
Advice to doctors: accidental ingestion, especially by a child, may lead to the occurrence of tachycardia, orthostatic hypotension, flushing of the face and headaches.

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.

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.

Overdose:
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.

Major incompatibilities:
Not applicable.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Increased heart rate[a,b]; Vomiting[b], Diarrhoea[c]; Anorexia (loss of appetite)[c], Lethargy[c]; Heart valve disorder[d].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Mucosa petechiae (pinpoint discoloration of mucosa due to bleeding)[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. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

For oral use.
Do not exceed the recommended dosage.
To ensure a correct dosage, bosy weight should be determined as accurately as possible.
The veterinary medicinal 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.													
Bodyweight (kg)	**1**	**2**	**4**	**5**	**10**	**15**	**20**	**25**	**30**	**35**	**40**	**50**	**60**
1.25 mg Fatrobendan Tablets	¼	½	¾	1	2								
5 mg Fatrobendan Tablets				¼	½	¾	1	1+ ¼	1 + ½	1 + ¾	2		
10 mg Fatrobendan Tablets					¼		½		¾		1	1 + ¼	1 + ½

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

9. Advice on correct administration

See section “Dosage for each species, route(s) and method of administration”.
Return any divided tablets to the blister pack.
Divided tablets should be used at the next administration.
Any divided tablets remaining after the last administration of the veterinary medicinal product should be discarded.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Return any divided tablets to the blister pack.
Divided tablets should be used at the next administration.
Do not use this veterinary medicinal product after the expiry date which is stated on the box and on the blister after Exp. The expiry date refers to the last day of the month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 11557/3003
Vm 11557/3004
Vm 11557/3005

Package sizes:

Fatrobendan 1.25 mg
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)

Fatrobendan 5 mg
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)

Fatrobendan 10 mg
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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
FATRO S.p.A.
Via Emilia, 285
40064 Ozzano dell'Emilia (Bologna), Italy.
Tel: +39 051 6512711

Local representative and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative/distributor of the marketing authorisation holder.

Approved: 17 July 2024

Gavin Hall