ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cardisan 1.25 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Active substance:
Pimobendan 1.25 mg

3. PACKAGE SIZE

30 tablets
60 tablets
90 tablets
100 tablets
120 tablets

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

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

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

14. MARKETING AUTHORISATION NUMBER(S)

Vm 36408/3011

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Aluminium blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cardisan 1.25 mg chewable tablets

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

pimobendan 1.25 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cardisan 1.25 mg chewable tablets for dogs
Cardisan 2.5 mg chewable tablets for dogs
Cardisan 5 mg chewable tablets for dogs
Cardisan 10 mg chewable tablets for dogs
Cardisan 15 mg chewable tablets for dogs

2. Composition

Each tablet contains:

Active substance:
Pimobendan 1.25 mg / 2.5 mg / 5 mg / 10 mg / 15 mg

Chewable tablet.
Light brown with brown spots, round and convex 8 / 10 / 13 / 18 / 20 mm flavoured tablet with a cross-shaped break line on one side. Tablets can be divided into 2 or 4 equal parts.

3. Target species

Dogs

4. Indications for use

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 pimobendan in cases of hypertrophic cardiomyopathies or in clinical conditions where an improvement in cardiac output is not possible for functional or anatomical reasons (e.g. aortic stenosis).
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in 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 “Adverse events”).
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 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.

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 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 product has not been assessed in nursing bitches.
Use only according to the benefit/risk assessment by the responsible veterinarian.

Interactions 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 beta-antagonists.

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):	Vomiting*[1] Diarrhoea*[2] Anorexia*[2] Lethargy*[2] Increased heart rate (slightly positive chronotropic effect)*[1] Increase in mitral valve regurgitation*[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Signs of effects on primary haemostasis: mucosa petechiae, subcutaneous haemorrhage*[4]

*[1] Effects are dose-dependent (can be avoided by reducing the dose).
*[2] Transient effect.
*[3] Observed during chronic pimobendan treatment in dogs with mitral valve disease.
*[4] These signs disappear when the treatment is withdrawn.

Reporting adverse events is important. It allows continuous safety monitoring of a 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 local representative of> the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

For oral use.
Do not exceed the recommended dosage.
Determine the bodyweight accurately before treatment to ensure correct dosage.
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.
One 2.5 mg chewable tablet in the morning and one 2.5 mg chewable tablet in the evening for a body weight of 10 kg.
One 5 mg chewable tablet in the morning and one 5 mg chewable tablet in the evening for a body weight of 20 kg.
One 10 mg chewable tablet in the morning and one 10 mg chewable tablet in the evening for a body weight of 40 kg.
One 15 mg chewable tablet in the morning and one 15 mg chewable tablet in the evening for a body weight of 60 kg.

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.

9. Advice on correct administration

Chewable tablets can be divided into four equal parts, for dosage accuracy, according to the bodyweight.
The product may be combined with a diuretic treatment, e.g. furosemide.

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.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after Exp. The expiry date refers to the last day of that month.

12. Special precautions for the 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 36408/3011

Cardisan 1.25 mg / 2.5 mg / 5 mg / 10 mg chewable tablets for dogs
Aluminium-OPA/Aluminium/PVC blisters containing 10 tablets

Cardisan 15 mg chewable tablets for dogs
Aluminium-OPA/Aluminium/PVC blisters containing 5 tablets.

Cardboard box of 30, 60, 90, 100 or 120 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>:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Manufacturer responsible for batch release:
Lelypharma B.V.
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

<Local representatives <and contact details to report suspected adverse reactions>:>
KELA VETERINARIA NV
Nieuwe Steenweg 62
9140 Elversele
Belgium
+32 3 780 63 90 Info.vet@kela.health

17. Other information

<to be completed nationally>

Approved 05 February 2025
Gavin Hall