PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cardisan 10 mg chewable tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:

Active substance:

Pimobendan 10 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.

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {month/year}

9. SPECIAL STORAGE PRECAUTIONS

Read the package leaflet before use.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/5014

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V
To be supplied only on veterinary prescription

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cardisan 10 mg chewable tablets

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

pimobendan 2.5 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE 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 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 known hypersensitivity to the active substance or to any of the excipients.

6. SPECIAL WARNING(S)

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

In rare cases a slight positively chronotropic effect (rise in heart rate) and vomiting can occur. However, these effects are dose-dependent and can be avoided by reducing the dose.

In rare cases transient diarrhoea, anorexia or lethargy have been observed.

Although a relationship with pimobendan has not been clearly established, in very rare cases, signs of effects on primary haemostasis (petechiae on mucous membranes, subcutaneous haemorrhages) may be observed during treatment. These signs disappear when the treatment is withdrawn. In rare cases, an increase in mitral valve regurgitation has been observed during chronic pimobendan treatment in dogs with mitral valve disease.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}". For details regarding the national system please contact NCA.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 PERIOD(S)

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 DISPOSAL

Dispose of waste material in accordance with local requirements.
Medicines should not be disposed of via wastewater.
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

Cardisan 1.25 mg chewable tablets for dogs Vm 36408/5011
Cardisan 2.5 mg chewable tablets for dogs Vm 36408/5012
Cardisan 5 mg chewable tablets for dogs Vm 36408/5013
Cardisan 10 mg chewable tablets for dogs Vm 36408/5014
Cardisan 15 mg chewable tablets for dogs Vm 36408/5015

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. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

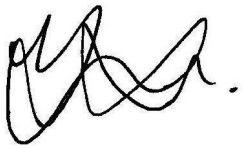
{DD/MM/YYYY}

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:
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

17. OTHER INFORMATION



Approved: 13 December 2022