PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cardisure flavoured 1.25 mg Tablets For dogs
Pimobendan

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tablet contains:
Active substance:
Pimobendan 1.25 mg

3. PHARMACEUTICAL FORM

Tablets [Already included in the product name]

4. PACKAGE SIZE

20/50/100/250 tablets

5. TARGET SPECIES

Dogs [Already included in the product name]

6. INDICATIONS

For the treatment of canine congestive heart failure originating from valvular insufficiency (mitral and/or tricuspid regurgitation) or dilated cardiomyopathy.

7. METHOD AND ROUTE OF ADMINISTRATION

For oral administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Return any divided tablet to the opened blister and use within 3 days.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 16849/4026

17. MANUFACTURER'S BATCH NUMBER

Lot:{number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cardisure flavoured 1.25 mg Tablets For dogs
Pimobendan

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

Lot: {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR:
Cardisure flavoured 1.25/2.5/5/10 mg
Tablets for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT:

Marketing authorisation holder:
Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:
Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel
The Netherlands

Dales Pharmaceuticals Limited
Snaygill Industrial Estate, Keighley Road, Skipton
North Yorkshire, BD23 2RW, United Kingdom

Genera Inc.
Svetonedeljska cesta 2, Kalinovica
10436 Rakov Potok, Croatia

Only the site testing and releasing the batches will be mentioned on the printed leaflet.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cardisure flavoured 1.25/2.5/5/10 mg Tablets for Dogs
Pimobendan

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

The active substance is pimobendan.

1.25 mg: 1 tablet contains 1.25 mg pimobendan
2.5 mg: 1 tablet contains 2.5 mg pimobendan
5 mg: 1 tablet contains 5 mg pimobendan
10 mg: 1 tablet contains 10 mg pimobendan

Light brown round tablets, scored on one side and plain on the other side.

4. INDICATIONS

For the treatment of canine congestive heart failure originating from valvular insufficiency (mitral and/or tricuspid regurgitation) or dilated cardiomyopathy.

5. CONTRAINDICATIONS

Do not use in cases of hypertrophic cardiomyopathies or clinical conditions where an augmentation of cardiac output is not possible for functional or anatomical reasons (e.g. aortic stenosis).

6. ADVERSE REACTIONS

A moderate positive chronotropic effect and vomiting may occur in rare cases. However, these effects are dose-dependent and may be avoided by reducing the dose in these cases. 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, effects on primary haemostasis (petechia on mucous membranes, subcutaneous haemorrhage) 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 displaying adverse reactions during the course of one treatment)
-common (more than 1 but less than 10 animals in 100 animals)
-uncommon (more than 1 but less than 10 animals in 1,000 animals)
-rare (more than 1 but less than 10 animals in 10,000 animals)
-very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

The tablets should be administered orally at a dose range of 0.2 mg to 0.6 mg pimobendan/kg body weight per day. The preferable daily dose is 0.5 mg pimobendan/kg body weight. The dose should be divided into two administrations (0.25 mg/kg body weight each), one half of the dose in the morning and the other half approximately 12 hours later. The maintenance dose should be individually adjusted according to the severity of the disease.

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

To break a tablet into two halves, place the tablet on an even surface with the scored side up, hold one half of the tablet and press down on the other half.

To break a double scored tablet into quarters, place the tablet on an even surface with the scored side up and apply pressure on the middle with your thumb.

Each dose should be given approximately one hour before feeding.

9. ADVICE ON CORRECT ADMINISTRATION

This product should be used only in dogs with cardiac insufficiency.
Do not exceed the recommended dosage.
Determine the bodyweight accurately before treatment to ensure correct dosage.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30°C.
Return any divided tablet to the opened blister and use within 3 days.

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

12. SPECIAL WARNINGS

Special warnings for each target species:

The product should be administered on an empty stomach at least one hour before meals, as absorption is reduced when given with feed.

Special precautions for use in animals:

The product is flavoured. To avoid accidental ingestion the tablets should be stored out of reach of dogs.
An *in vitro* study in rat tissue demonstrated that pimobendan increased glucose-induced insulin release from pancreatic β-cells in a dose-dependent manner. If the product is administered to diabetic dogs, blood glucose levels should be carefully monitored.

As pimobendan is metabolised in the liver, particular care should be taken when administering the product to dogs with severe hepatic insufficiency.
Monitoring of cardiac function and morphology is recommended in animals treated with pimobendan.(See also section 6).

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

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.

Use during pregnancy or 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 they have 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.

Interaction with other medicinal products and other forms of interaction:

In pharmacological studies no interaction between the cardiac glycoside ouabain and pimobendan was detected. The pimobendan-induced increase in contractility of the heart is attenuated in the presence of the calcium antagonist verapamil and the β-antagonist propranolol.

Overdose (symptoms, emergency procedures, antidotes):

In the case of overdose, a positive chronotropic effect and vomiting may occur. In this situation, the dosage should be reduced and appropriate symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

When used in cases of 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 dilated cardiomyopathy in conjunction with furosemide, enalapril and digoxin, the product has been shown to improve the quality of life and to extend life expectancy in treated dogs.

Package sizes:
Aluminium – PVC/PE/PVDC blister:
10 tablets per blister: 2, 5, 10 or 25 blisters per carton.

Aluminium – Aluminium blister:
1.25 and 2.5 mg tablet: 10 tablets per blister: 2, 5, 10 or 25 blisters per carton.
5 and 10 mg tablet: 5 tablets per blister: 4, 10, 20 or 50 blisters per carton.

Not all pack sizes may be marketed.

Approved: 17 January 2019