LABELLING AND PACKAGE LEAFLET

PIMOCARD TABLETS

(2.5 mg tablets)

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pimocard 2.5 mg flavoured tablets for dogs

Pimobendan

2. STATEMENT OF ACTIVE SUBSTANCES

1 tablet contains:
Active substance:
Pimobendan 2.5 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

20 / 50 / 100 / 250 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

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 SIGHT AND REACH 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 16849/4043

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pimocard 2.5 mg flavoured 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:
Pimocard 1.25 / 2.5 / 5 / 10 mg flavoured 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

Manufacturers 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

Pimocard 1.25 / 2.5 / 5 / 10 mg flavoured tablets for dogs
Pimobendan

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 tablet contains:
Active substance:
Pimobendan 1.25 / 2.5 / 5 / 10 mg

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

4. INDICATION

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 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 'Use during pregnancy or lactation' under 'Special warnings' section.

6. ADVERSE REACTIONS

A slight positively chronotropic effect (rise in heart rate) and vomiting can occur in rare cases. However, these effects are dose-dependent and can be avoided by reducing the dose.
Transient diarrhoea, anorexia or lethargy have been observed in rare cases.
An increase in mitral valve regurgitation has been rarely observed during chronic pimobendan treatment in dogs with mitral valve disease.
Signs of effects on primary haemostasis (petechiae on mucous membranes, subcutaneous haemorrhages) may be observed during treatment in very rare cases,. although a relationship with pimobendan has not been clearly established. These signs disappear when the treatment is withdrawn.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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.

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. Each dose should be given approximately one hour before feeding.

The product may be combined with a diuretic treatment such as furosemide.

To break a single scored 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.

9. ADVICE ON CORRECT ADMINISTRATION

This product should be used only in dogs with cardiac insufficiency.
Do not exceed the recommended dosage.
Determine the body weight 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 blister and carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special precautions for use in animals:
Blood glucose should be tested regularly during treatment in dogs with existing diabetes mellitus.
Monitoring of cardiac function and morphology is recommended in animals treated with pimobendan.
See also the ‘Adverse reactions’ section.

The 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:
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.
This product may cause cardiovascular effects in the event of accidental ingestion.

Use during pregnancy or lactation:
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic or foetotoxic effect. 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 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 diltiazem and the β-antagonist propranolol.

Overdose (symptoms, emergency procedures, antidotes):
An overdose may cause vomiting, a positive chronotropic effect, apathy, ataxia, heart murmurs or hypotension. 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.

Incompatibilities:
Not applicable.

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

DD-MM-YYYY

15. OTHER INFORMATION

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.

When used in a limited number of cases of symptomatic dilated cardiomyopathy in conjunction with furosemide, enalapril and digoxin, the veterinary medicinal product

has been shown to improve the quality of life and to extend life expectancy in treated dogs.

20, 50, 100 or 250 tablets per carton.
Not all pack sizes may be marketed.
To be supplied only on veterinary prescription.

National item

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

Approved: 17 January 2019