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Zelys® 1.25 mg, 5mg and 10mg chewable tablets for dogs

Species: Dogs

Therapeutic indication:Pharmaceuticals: Cardiovascular and respiratory preparations

Active ingredient: Pimobendan

Product: Zelys® 1.25 mg, 5mg and 10mg chewable tablets for dogs

Product index: Zelys®

Incorporating:

Qualitative and quantitative composition

Each tablet contains:

Active substance:

Pimobendan 1.25 mg, 5mg or 10mg

Excipients:

For the full list of excipients, see Pharmaceutical particulars

Pharmaceutical form

Chewable tablet. Round in shape beige to light brown tablet, with single score line on one side. The tablets can be divided into two equal parts.

Clinical particulars

Target species

Dogs

Indications for use, specifying the target species

For the treatment of canine congestive heart failure originating from valvular insufficiency (mitral and/or tricuspid valve regurgitation) or dilated cardiomyopathy. (See also Amounts to be administered and administration route).

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, lactation or lay).

Special warnings for each target species

None.

Special precautions for use

Special precautions for use in animals

The 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 Adverse reactions)

The chewable 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

Accidental ingestion, especially by a child, may lead to the occurrence of tachycardia, orthostatic hypotension, flushing of the face and headaches.

Unused part-tablets should be returned to the open blister space, or to the bottle and inserted back into the outer packaging. Keep in a safe place out of the sight and reach of children.

Close bottle tightly with cap directly after removal of the required number of tablets or part-tablets.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Adverse reactions (frequency and seriousness)

Rare (1 to 10 animals / 10,000 animals treated):	Vomiting1, Diarrhoea2, Anorexia2, Le valve disorder3
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Mucosa petechiae4, Haemorrhage4,5

1 Dose-dependent and can be avoided by reducing the dose.

2 Transient

3 An increase in mitral valve regurgitation has been observed during chronic pimobendan treatment in dogs with mitral valve disease.

4 Although a relationship with pimobendan has not been clearly established, these signs of effects on primary haemostasis disappear when the treatment is withdrawn.

5 Subcutaneous

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Use during pregnancy, lactation or lay

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 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 glycosides 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.

Amounts to be administered and administration route

Do not exceed the recommended dosage.

Determine the bodyweight accurately before treatment to ensure correct dosage.

The tablets should be administered orally at a dose range of 0.2 mg to 0.6 mg pimobendan/kg bodyweight per day. The preferable daily dose is 0.5 mg pimobendan/kg bodyweight. The dose should be divided into two administrations (0.25 mg/kg bodyweight each), using a suitable combination of whole, or half of tablets. 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. Spontaneous intake by the animal or place the tablet behind the lingual torus.

This corresponds to:

One 1.25 mg chewable tablet in the morning and one 1.25 mg chewable tablet in the evening for a bodyweight of 5 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.

Tablets are divisible in 2 for the 1.25, 5 and 10 mg tablet.

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

Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

Withdrawal period(s)

Not applicable.

Pharmacological particulars

Pharmacotherapeutic group: Cardiac stimulant, excl. cardiac glycosides, phosphodiesterase inhibitor. ATCvet code: QC01CE90.

Pharmacodynamic properties

Pimobendan, a benzimidazole-pyridazinone derivative, is a non-sympathomimetic, non-glycoside inotropic substance with potent vasodilatative properties.

Pimobendan exerts its stimulatory myocardial effect by a dual mechanism of action: increase in calcium sensitivity of cardiac myofilaments and inhibition of phosphodiesterase (type III). It also exhibits a vasodilating action through an inhibitory action on phosphodiesterase III activity. Thus the positive inotropism is triggered neither by an action similar to that of the cardiac glycosides nor sympathomimetically.

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

Pharmacokinetic particulars

Following oral administration of pimobendan, the absolute biovailability of the active principle is 60 - 63%. Since this bioavailability is considerably reduced when pimobendan is administered with food or shortly thereafter, it is recommended to treat animals approximately 1 hour before feeding.

After oral administration of 0.25 mg/kg b.w of pimobendan, the maximal plasma concentration was 17.4 µg/L (mean Cmax) and AUC was 20.9 h*µg/L (mean AUC0-t).

The volume of distribution is 2.6 l/kg, indicating that pimobendan is distributed readily into the tissues. The mean plasma protein binding is 93%.

The compound is oxidatively demethylated to its major active metabolite (UD-CG 212). Further metabolic pathways are phase II conjugates of UD-CG 212, in essence glucuronides and sulfates.

The plasma elimination half-life of pimobendan is 0.4 hours, consistent with the high clearance of 90 ml/min/kg and a short mean residence time of 0.5 hours.

The main active metabolite is eliminated with a plasma elimination half-life of 2.0 hours. Almost the entire dose is eliminated via faeces.

Pharmaceutical particulars

List of excipients

Silica colloidal anhydrous, Stearic acid, Copovidone, Croscarmellose sodium, Malic acid, Maize starch, Cellulose microcrystalline, Lactose monohydrate, Dried Yeast (from *Saccharomyces cerevisiae*), Pig liver powder

Major incompatibilities

Not applicable.

Shelf life

For blisters:

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

For bottle:

Shelf life of the veterinary medicinal product as packaged for sale:

1.25 mg: 2 years

5mg and 10mg: 18 months

Shelf life after first opening the immediate packaging:

1.25 mg and 10mg: 2 months

5mg: 4 months

Special precautions for storage

For blisters:

Any unused tablet portion should be returned to the blister and be used for the next administration.

Do not store above 30 °C.

For bottle:

Keep the bottle tightly closed in order to protect from moisture.

Any unused tablet portion should be returned to the bottle and be used for the next administration.

Do not store above 25 °C.

Nature and composition of immediate packaging

1.25 mg:

For blisters: Polyamide-Aluminium-Polyvinyl chloride / aluminium heat sealed blisters. Cardboard box with 3 or 8 blisters of 12 tablets.

For bottle: High density polyethylene screw bottles with a polypropylene child resistant closure – twist off cap. 35 ml bottle contains 60 tablets.

5mg:

For blisters: Polyamide-Aluminium-Polyvinyl chloride / aluminium heat sealed blisters. Cardboard box with 5 or 16 blisters of 6 tablets

For bottle: High density polyethylene screw bottles with a polypropylene child-resistant closure – twist off cap. 150 ml bottle contains 60 tablets

10mg:

For blisters: Polyamide-Aluminium-Polyvinyl chloride / aluminium heat sealed blisters. Cardboard box with 8 or 24 blisters of 4 tablets

For bottle: High density polyethylene screw bottles with a polypropylene child resistant closure – twist off cap. 150 ml bottle contains 30 tablets

Not all pack sizes may be marketed.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Marketing Authorisation Holder (if different from distributor)

Marketing Authorisation Number

1.25 mg:

GB Vm 14966/5085

NI Vm 14966/3084

5 mg:

GB Vm 14966/5086

NI Vm 14966/3085

10 mg:

GB Vm 14966/5087

NI Vm 14966/3086

Significant changes

Date of the first authorisation or date of renewal

11 June 2018

Date of revision of the text

November 2025

Any other information

Nil

Legal category

Legal category:POM-V

GTIN

GTIN description: Zelys 1.25 mg 8X12T

GTIN:03411113046040

GTIN description: Zelys 5 mg 16X6T

GTIN:03411113046057

GTIN description: Zelys 10 mg 24X4T

GTIN:03411113046064