1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cardisure 3.5 mg/ml oral solution for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Pimobendan 3.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	1.0 mg
Glycerol	
Macrogol 300	
Povidone K90	
Propylene glycol	
Acesulfame potassium (E950)	
Steviol glycosides (E960)	

Clear, colourless, semi-viscous liquid.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

3.3 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).
Do not use in dogs with severe impairment of liver function, as pimobendan is metabolised mainly via the liver.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None known.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 section 3.6).

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. To avoid accidental ingestion, do not leave the filled syringe unattended, Store the bottle and used syringe in the original carton in order to prevent children from getting access to the veterinary medicinal product. Close bottle tightly with cap directly after removal of the required amount of liquid. The veterinary medicinal product must be used and kept out of sight and reach of children.

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

This veterinary medicinal product is a skin sensitizer. Handle this veterinary medicinal product with care to avoid exposure to the skin. Wash hands after use.

People with known hypersensitivity to pimobendan or any of the excipients should avoid contact with the veterinary medicinal product. In case of accidental spillage on skin, wash off immediately with soap and water.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	Increased heart rate[a,b], Increase in mitral valve regurgitation[c] Vomiting[b], Diarrhoea[d] Anorexia[d], Lethargy[d]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Mucosa petechiae[e], Haemorrhage (subcutaneous)[e]

[a] Slight positively chronotropic effect.

[b] These effects are dose-dependent and can be avoided by reducing the dose.

[c] Has been observed during chronic pimobendan treatment in dogs with mitral valve disease.

[d] Transient.

[e] Although a relationship with pimobendan has not been clearly established, signs of effects on primary haemostasis may be observed during treatment. These signs disappear when the treatment is withdrawn.

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Pregnancy and lactation:
Use only according to the benefit-risk assessment by the responsible veterinarian.
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.

3.8 Interaction with other medicinal products and other forms of interaction

The pimobendan-induced increase in contractility of the heart is attenuated in the presence of the calcium antagonists verapamil and diltiazem and by the β-antagonist propranolol.

In pharmacological studies no interaction between the cardiac glycoside ouabain and pimobendan was detected.

3.9 Administration routes and dosage

Oral use.

Administration of pimobendan should take place approximately one hour before feeding.
The veterinary medicinal product should be administered orally at a dose of 0.2 mg to 0.6 mg pimobendan/kg body weight per day. The daily dose should be divided into two equal administrations (i.e. 0.1 mg to 0.3 mg pimobendan/kg body weight equivalent to 0.3 ml to 0.8 ml of veterinary medicinal product per 10 kg body weight, twice daily); one half of the dose in the morning and the other half approximately 12 hours later.

The preferable daily dose is 0.5 mg pimobendan/kg body weight divided into two doses, every 12 hours (i.e. 0.25 mg/kg equivalent to 0.7 ml of veterinary medicinal product per 10 kg body weight, per administration).

The veterinary medicinal product can be given directly into the mouth using the measuring syringe provided in the package.

To ensure a correct dosage, body weight should be determined as accurately as possible. The syringe provided with the veterinary medicinal product is not appropriate for the treatment of dogs below 3.5 kg (posology below 0.1 ml).

In cases of mild congestive heart failure, a daily dose at the lower end of the dose range may be adequate. If, however, a clear response is not observable within one week, the dosage should be raised.

The maintenance dose should be individually adjusted by the responsible veterinarian according to the severity of the disease.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QC01CE90

4.2 Pharmacodynamics

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 vasodilatory 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 valvular insufficiency in conjunction with furosemide, the veterinary medicinal 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 large breed dogs in conjunction with concomitant standard therapy, the veterinary medicinal product has been shown to improve the quality of life and to extend life expectancy in treated dogs.

4.3 Pharmacokinetics

Following oral administration of pimobendan the absolute bio-availability of the active principle is 60 - 63%. Bio-availability is considerably reduced when pimobendan is administered with food.

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 sulphates.

The plasma elimination half-life of pimobendan is 0.8 hours which is consistent with a high clearance and a short mean residence time.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 60 days.

5.3 Special precautions for storage

Keep the bottle and syringe in original carton in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.

5.4 Nature and composition of immediate packaging

Brown high-density polyethylene bottles fitted with white polypropylene child resistant caps, and low-density polyethylene syringe adaptors.
A low-density polyethylene oral dosing syringe with graduations is supplied with the veterinary medicinal product.

Pack sizes:
Carton box containing 1 bottle of 42 ml and a 1.5 ml dosing syringe.
Carton box containing 1 bottle of 168 ml and a 3 ml dosing syringe.

Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA22622/026/001

8. DATE OF FIRST AUTHORISATION

13/09/2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

21/08/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).