Summary of Product Characteristics

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 substance:		
Pimobendan	3.5	mg
Excipients:		
Benzyl alcohol (E1519)	1.0	mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution.
Clear, colourless, semi-viscous liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

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

4.3 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 known hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None known.

4.5 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 section 4.6).

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 and store the bottle and used syringe in the original carton in order to prevent children from getting access to the product. Close bottle tightly with cap directly after removal of the required amount of liquid. The 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 product is a skin sensitizer. Handle this product with care to avoid exposure to the skin. Wash hands after use.
People with known hypersensitivity to pimobendan or any of the excipients in this product should avoid exposure to the skin.
In case of accidental spillage on skin, wash off immediately with soap and water.

4.6 Adverse reactions (frequency and seriousness)

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.
In rare cases, an increase in mitral valve regurgitation has been observed during chronic pimobendan treatment in dogs with mitral valve disease.
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.

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)

4.7 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.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

For oral use.
Administration of pimobendan should take place approximately one hour before feeding.
The product should be administered orally at a dose of 0.2 mg to 0.6 mg pimobendan/kg bodyweight per day. The daily dose should be divided into two equal administrations (i.e. 0.1 mg to 0.3 mg pimobendan/kg bodyweight equivalent to 0.3 ml to 0.8 ml of product per 10 kg bodyweight, 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 product per 10 kg bodyweight, per administration).
The product can be given directly into the mouth using the measuring syringe provided in the package.
Determine the bodyweight accurately before prescribing to ensure administration of the correct dosage. The syringe provided with the product is not appropriate for the treatment of dogs below 3.5 kg (posology below 0.1ml)
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 product may be combined with a diuretic, e.g. furosemide.

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

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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Cardiac stimulant excl. cardiac glycosides phosphodiesterase inhibitor.
ATC vet code: QC01CE90.

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

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Glycerol
Macrogol 300
Povidone K90
Propylene glycol
Acesulfame potassium (E950)
Steviol glycosides (E960)

6.2 Major incompatibilities

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

6.3 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

6.4 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.

6.5 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 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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.

7 MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA22622/026/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 September 2019

10 DATE OF REVISION OF THE TEXT

February 2022