

Pimobendán[®]

Brouwer Tablets

FOR VETERINARY USE
Prescription medication

Pimobendan based palatable tablets for dogs.

Composition:

Each 700 mg tablet contains 2.5 mg Pimobendan and excipients q.s.p. 700 mg.

Each 1400 mg tablet contains 5 mg Pimobendan and excipients q.s.p. 1400 mg.

Each 2800 mg tablet contains 10 mg Pimobendan and excipients q.s.p. 2800 mg.

Indications:

- Inotrope.

- Treatment of congestive heart failure in dogs (CHF) caused by atrioventricular valve failure or by dilated cardiomyopathy.

- Treatment of preclinical dilated cardiomyopathy (asymptomatic with dilated left ventricular end-systolic and end-diastolic diameters) in Doberman Pinschers, following diagnosis of cardiopathy by echocardiogram.

Administration and form of use: The product is administered exclusively by the oral route. Administrate each dose approximately one hour before meals. The quadrisectioned tablet can be divided into 4 equal parts, allowing correct adjustment of the dose.

Dosing: The effective oral doses of Pimobendan range from 0.2 to 0.6 mg/kg/day, with a recommended dose of 0.5 mg/kg divided in two daily administrations (0.25 mg/kg Pimobendan at 12 hour intervals), equivalent to:

700 mg tablets (2.5 mg Pimobendan):

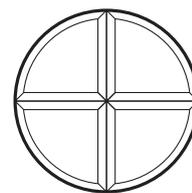
- Animals weighing 2.5 to 5 kg: ¼ - ½ tablet every 12 hours
- Animals weighing 5.1 to 10 kg: ½ - 1 tablet every 12 hours.

1400 mg tablets (5 mg Pimobendan):

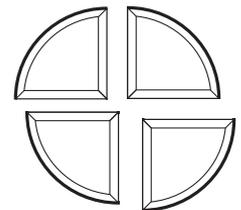
- Animals weighing 10.1 to 20 kg: ½ - 1 tablet every 12 hours.

2800 mg tablets (10 mg Pimobendan):

- Animals weighing 20.1 to 40 kg: ½ - 1 tablet every 12 hours.



Quadrisectioned
tablet



Tablet divided
into four equal parts

Given the type of pathology treated, treatment is usually for life. However, the Veterinary Doctor involved shall establish the duration of treatment based on the specific characteristics of each case.

Side effects:

- Pimobendan is generally well tolerated and has scarce side effects at the recommended doses.

- A slight increase in heart rate and vomiting may occur on rare occasions. These effects depend on the dose used, and may be avoided by reducing the dose.

- In some cases it may cause hypotension at low doses and tachycardia at high doses.

- On rare occasions it may cause transitory diarrhea, anorexia or lethargy.

- Although no clear relationship has been proven to exist with Pimobendan, on very rare occasions effects have been observed on primary hemostasis (petechiae on mucous membranes, subcutaneous hemorrhages) during treatment. These effects disappear when treatment is discontinued.

- On rare occasions an increase in mitral valve regurgitation has been observed during chronic treatment with Pimobendan in dogs with mitral valve failure.

- It may cause systolic failure due to its calcium sensitizing effect, causing cardiac muscle rigidity (positive lusitropic effect).

Contraindications and restrictions on use:

- Do not use for treating hypertrophic cardiopathies or diseases where augmentation of cardiac output is inappropriate for functional or anatomical reasons (e.g: aortic stenosis).

- Since Pimobendan is mainly metabolized in the liver, it should not be administered to dogs with severe liver failure.

- Do not administrate in cases of hypersensitivity to Pimobendan.

- The active ingredient has not been tested in cases of asymptomatic dilated cardiomyopathy in Dobermans with auricular fibrillation or sustained ventricular tachycardia.

- The safety of Pimobendan has not been established in puppies aged less than 6 months, dogs used for breeding, or pregnant or lactating bitches. In these cases, a risk-benefit assessment should be carried out by the veterinary professional involved.

Drug interactions:

- The medicinal product can be administered with furosemide, Angiotensin-converting enzyme (ACE) inhibitors (eg: Benazepril), and spironolactone.
- No interaction has been observed between the cardiac glycoside Strophanthin and Pimobendan.
- Calcium channel blockers such as verapamil and diltiazem, and beta blockers, can reduce the positive inotropic action of Pimobendan. When necessary, the dose of Pimobendan may be increased within the recommended range.
- Pimobendan does not have an antiarrhythmogenic effect and can be administered with any antiarrhythmic drug.

Overdose:

Symptoms: may produce tachycardia and vomiting.

Emergency behavior: reduce the dose and start appropriate symptomatic treatment.

Antidote: there is no specific treatment or antidote.

Special precautions for use in animals:

- Each dose shall be administered approximately one hour before meals.
- Safety of use in dogs with diabetes mellitus has not been evaluated, therefore, when a veterinary professional considers that treatment is advisable following a risk-benefit assessment, blood glucose shall be measured regularly during treatment in dogs with diabetes mellitus.
- The safety of Pimobendan has not been established in dogs with congenital heart defects or other serious metabolic diseases. In such cases, a risk-benefit assessment shall be conducted by the veterinarian involved.
- Follow-up of heart function and morphology is recommended in dogs treated with Pimobendan.
- For use in the preclinical stage of dilated cardiomyopathy (asymptomatic with dilated left ventricular end-systolic and end-diastolic diameters), the diagnosis shall be made with a full heart evaluation (including echocardiogram and Holter test, where possible).

General precautions:

- People with a known hypersensitivity to Pimobendan should avoid contact with the veterinary product.
- Wash hands after using the product.
- The product should be kept in its original container, perfectly closed to protect from dampness.
- Keep away from reach of children and animals.
- After use, dispose of container as household waste.

Intoxication in humans:

In case of accidental ingestion, consult a doctor immediately and show the product packaging or insert.

Note for doctor: accidental ingestion, especially in children, may cause tachycardia, orthostatic hypotension, flushed face and headache.

National Toxicology Center: Tel.: 0800-333-0160. Keep away from reach of children and animals.

Pharmaceutical forms:

- 700 mg tablets containing 2.5 mg Pimobendan for treating dogs weighing 2.5 to 10 kg.
- 1400 mg tablets containing 5 mg Pimobendan for treating dogs weighing 10.1 to 20 kg.
- 2800 mg tablets containing 10 mg Pimobendan for treating dogs weighing 20.1 to 40 kg.

Store at room temperature between 15 ° and 30 °C.

 **senasa** - Certificate No. 17-136
Manuf. Plant No. 4384 - Made in Argentina.

Manufactured by BROUWER S.A.

Technical Direction: Rodolfo A. M. Perotti. Veterinary doctor, License No. 2705.

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www.brouwer.com.ar