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Libeo 10 mg and 40 mg chewable tablets for dogs

Species:	Dogs
Therapeutic indication:	**Pharmaceuticals:** Cardiovascular and respiratory preparations
Active ingredient:	Frusemide (Furosemide)
Product:	Libeo 10 mg and 40 mg chewable tablets for dogs
Product index:	Libeo

Presentation

Chewable, clover shape beige tablet. The tablets can be divided into equal quarters.

Libeo 10 mg tablet contains 10 mg furosemide

Libeo 40 mg tablet contains 40 mg furosemide

Uses

For the treatment of ascites and oedema, particularly associated with cardiac insufficiency in dogs.

Dosage and administration

Oral route.

1 to 5 mg furosemide/kg bodyweight daily, i.e 0.5 to 2.5 tablets per 5 kg bodyweight for Libeo 10 mg, one to two times daily depending on the severity of the oedema or ascites.

1 to 5 mg furosemide/kg bodyweight daily, i.e 0.5 to 2.5 tablets per 20 kg bodyweight for Libeo 40 mg, one to two times daily depending on the severity of the oedema or ascites

Dosages are as follows:

Weight in kg	Number of Libeo 10 mg tablets	Number of Libeo 40 mg tablets
2 - 3.5	1/4	Use Libeo 10 mg
3.6 - 5	1/2	Use Libeo 10 mg
5.1 - 7.5	3/4	Use Libeo 10 mg
7.6 - 10	1	1/4
10.1 - 12.5	1 ¼	Use Libeo 10 mg
12.6 - 15	1 ½	Use Libeo 10 mg
15.1 - 20	Use Libeo 40 mg	1/2
20.1 - 30	Use Libeo 40 mg	3/4
30.1 - 40	Use Libeo 40 mg	1
40.1 - 50	Use Libeo 40 mg	1 ¼

For maintenance, the dosage should be adapted to the lowest effective dose by the veterinarian depending on the clinical response of the dog to the therapy. The dosage and schedule may have to be adjusted depending on the condition of the animal. If treatment is administered last thing at night this may result in inconvenient diuresis overnight.

Instruction on how to divide the tablet: Put the tablet on a plain surface, with its scored side facing the surface (convex face up). With the tip of forefinger, exert a slight vertical pressure on the middle of the tablet to break it in its width into halves. In order to obtain quarters, then exert a slight pressure on the middle of one half with forefinger to break it in its length.

The tablets are flavoured and may be mixed with a small amount of food offered prior to the main meal, or administered directly into the mouth.

Contra-indications, warnings, etc

Do not use the product in dogs suffering from hypovolaemia, hypotension or dehydration.

Do not use in cases of renal failure with anuria.

Do not use in cases of electrolyte deficiency.

Do not use in cases of known hypersensitivity to furosemide, sulfonamides or any of the excipients.

Special warnings for each target species

Therapeutic efficacy may be impaired by increased intake of drinking water. Where the animal's condition permits, water intake should be restricted to physiologically normal levels during treatment.

Special precautions for use in animals

As the tablets are flavoured, they should be stored in a safe place out of the reach of animals.

Furosemide should be used with caution in case of pre-existing electrolyte and/or water imbalance, impaired hepatic function (may precipitate hepatic coma) and diabetes mellitus. In case of prolonged treatment, hydration status and serum electrolytes should be monitored frequently.

1-2 days before and after commencement of treatment with diuretics and ACE inhibitors renal function and hydration status should be monitored.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to furosemide should avoid contact with the veterinary medicinal product. Wash hands after use.

Do not handle this product if you know you are sensitive to sulphonamides as hypersensitivity to sulphonamides may lead to hypersensitivity to furosemide. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

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

Adverse reactions

Cross-reactivity to sulfonamides is possible.

In rare cases, soft faeces may occur. These signs are transient and mild and do not necessitate the withdrawal of the treatment.

Due to the diuretic action of furosemide, there may be hemoconcentration and impairment of the circulation. In cases of prolonged treatment electrolyte deficiency (including hypokalemia, hyponatremia) and dehydration may occur.

Overdose

Doses higher than recommended may cause transitory deafness, electrolyte and water balance problems CNS effects (lethargy, coma, seizures) and cardiovascular collapse. Treatment should be symptomatic.

Use during pregnancy, lactation or lay

Laboratory studies have produced evidence of teratogenic effects.

The safety of the product has not been established in pregnant and lactating bitches however, furosemide is excreted into milk.

In pregnant and lactating animals, use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

Concurrent use with drugs affecting electrolyte balance (corticosteroids, other diuretics, amphotericin B, cardiac glycosides) requires careful monitoring. Concomitant use with aminoglycosides or cephalosporins may increase the risk of nephrotoxicity. Furosemide may increase the risk of sulfonamide allergy. Furosemide may alter insulin requirements in diabetic animals. Furosemide may reduce the excretion of NSAIDs. The dose regimen may need to be modified for long term treatment in combination with ACE inhibitors, depending upon the animal's response to therapy.

Pharmaceutical precautions

Any part-used tablet should be used within 72 hours. Do not store above 30°C. Any part-used tablet should be returned to the opened blister.

Legal category

Legal category: POM-V

Packaging quantities

Libeo 10 mg tablets: Pack sizes of 10, 20, 100, 120 or 200 tablets in blisters of 10 tablets.

Libeo 40 mg tablets: Pack sizes of 8, 16, 96, 120 or 200 tablets in blisters of 8 tablets.

Not all pack sizes may be marketed.

Further information

Pharmacodynamic properties

Furosemide is a potent loop diuretic that increases urinary volume. It inhibits electrolyte resorption in the proximal and distal renal tubules and in the ascending Loop of Henle. Excretion of sodium ions, chloride ions and to a lesser extent, potassium ions is enhanced, as is water excretion. Furosemide has no effect on carbonic anhydrase.

Pharmacokinetic particulars

Furosemide is excreted unchanged in the urine.

After oral administration of the product (5 mg/kg), furosemide is rapidly absorbed with maximum plasma levels (Cmax of 2126ng/mL) occurring within 1.1 hour. The terminal half life of elimination is 2.6 hours.

Furosemide is predominantly eliminated via the kidneys in the urine (70 %) and via the faeces. Plasma protein binding of furosemide is 91% and estimated distribution volume is 0,52 L/kg. Furosemide metabolizes in very small amounts (main metabolite: 4-chloro-5-sulfamoyl-anthranilic-acid, no diuretic activity).

In dogs, after oral administration, furosemide causes a dose-dependent increase in urine volume starting 1 hour after administration, reaching a maximum 2-3 hours post administration and lasting approximately 6 hours.

Marketing Authorisation Number

Libeo 10 mg tablets

Vm: 15052/4104

Libeo 40 mg tablets

Vm: 15052/4105

Significant changes

GTIN

GTIN description:	Libeo 10 mg tablets
GTIN:	03411112273553
GTIN description:	Libeo 40 mg tablets
GTIN:	03411112273584