

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Libeo 40 mg chewable tablets for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet of 1320 mg contains:

Active substance:

Furosemide..... 40 mg

Excipients:

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet.

Clover shape beige tablet. The tablets can be divided into equal quarters.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

Treatment of ascites and oedema, particularly associated with cardiac insufficiency.

4.3 Contraindications

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

4.4 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.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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.

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 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.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

Oral route.

1 to 5 mg furosemide/kg bodyweight per day, i.e ½ to 2.5 tablets per 20 kg bodyweight of the product, given in a single dose or in two divided daily doses. Depending on the severity of the oedema or ascites or in refractory cases, the daily dose may be doubled.

Example for a targeted dose of 1mg/kg per administration:

	Tablets per administration
	LIBEO 40 mg
7.6 – 10 kg	1/4
10.1-12.5 kg	Use Libeo 10 mg
12.6 – 15 kg	Use Libeo 10 mg
15.1 – 20 kg	1/2
20.1 – 30 kg	¾
30.1 – 40 kg	1
40.1 – 50 kg	1 1/4

For dogs of 2 to 7.5 and dogs of 10.1 to 15 kg bodyweight, use Libeo 10 mg tablets.

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.

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

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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: diuretics, furosemide

ATC Vet Code: QC03CA01

5.1 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.

5.2 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 (C_{max} 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chicken flavour
Yeast extract (*Saccharomices cerevisiae*)
Maltodextrine
Magnesium stearate
Silica, colloidal anhydrous
Microcrystalline cellulose
Sodium croscarmellose
Lactose monohydrate

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Any part-used tablet should be used within 72 hours

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

(white PVC –PVDC – aluminium heat sealed) containing 8 tablets per blister
Cardboard box of 8 tablets containing 1 blister of 8 tablets
Cardboard box of 16 tablets containing 2 blisters of 8 tablets

Cardboard box of 96 tablets containing 12 blisters of 8 tablets
Cardboard box of 120 tablets containing 15 blisters of 8 tablets
Cardboard box of 200 tablets containing 25 blisters of 8 tablets

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 products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Ceva Santé Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10815/037/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st February 2014
Date of last renewal: 14th December 2018

10 DATE OF REVISION OF THE TEXT

September 2018