

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Cardboard box)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Libeo 40 mg chewable tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains:
Furosemide 40 mg

3. PACKAGE SIZE

Cardboard box with 8 tablets
Cardboard box with 16 tablets
Cardboard box with 96 tablets
Cardboard box with 120 tablets
Cardboard box with 200 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {month/year}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

Any part-used tablet should be returned to the opened blister and used within 72 hours

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBERS

Vm 14966/5042

Vm 14966/3041

15. BATCH NUMBER

Lot

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS (BLISTERS)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Libeo



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

40 mg of furosemide

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Libeo 40 mg Chewable Tablets for Dogs

2. Composition

Each tablet of 1320 mg contains:

Active substance:

Furosemide 40 mg

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

3. Target species

Dogs

4. Indications for use

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

5. 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.

6. Special warnings

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 safe use in the target species

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.

Special precautions for the protection of the environment:

No applicable

Pregnancy and lactation:

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.

Cross reactivity to sulfonamides is possible.

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.

7. Adverse events

Dog:

Rare (1 to 10 animals / 10,000 animals treated):	Soft stool ¹ Dehydration ² , Electrolyte disorder ² (e.g. hypokalaemia, hyponatremia)
Undetermined frequency (cannot be estimated from the available data)	Haemoconcentration ³ Poor peripheral circulation ³

¹ Transient, mild, do not necessitate the withdrawal of the treatment

² In cases of prolonged treatment

³ Due to the diuretic action of furosemide

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use.

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

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

9. Advice on correct administration

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.

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.

10. Withdrawal periods

Not applicable

11. Special storage precautions

Keep out of the sight and reach of children. Do not store above 30°C.

Any part-used tablet should be returned to the opened blister and used within 72 hours.

Do not use after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 14966/5042
Vm 14966/3041

Pack sizes:

Cardboard box with 8 tablets
Cardboard box with 16 tablets
Cardboard box with 96 tablets
Cardboard box with 120 tablets
Cardboard box with 200 tablets
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing Authorisation Holder:

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Contact details to report suspected adverse reactions:

Ceva Animal Health Ltd
Explorer House, Mercury Park
Wycombe Lane, Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom
Tel. 01628 334056
email technicalandpvuk-group@ceva.com

Manufacturer responsible for batch release:

Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 LOUVERNE
FRANCE
Email: pharmacovigilance@ceva.com

17. Other information

POM-V

Veterinary Medicinal product subject to prescription
For animal treatment only

Gavin Hall
Approved: 03 October 2025