1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LIBEO 40 MG CHEWABLE TABLETS FOR DOGS
LIBEO 40 mg (FR)
LIBEO VET (DK, FI,SE)
Furosemide

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet of 1320 mg contains:
Active substance:
Furosemide .....40 mg

3. PHARMACEUTICAL FORM

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

4. 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

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4105

17. MANUFACTURER'S BATCH NUMBER

Batch:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LIBEO 40 MG CHEWABLE TABLETS FOR DOGS
LIBEO 40 mg (FR)
LIBEO VET (DK, FI, SE)
Furosemide

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva logo

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch:

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

LIBEO 40 MG CHEWABLE TABLETS FOR DOGS

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

Manufacturer responsible for batch release:

Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 LOUVERNE
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

LIBEO 40 MG CHEWABLE TABLETS FOR DOGS
LIBEO 40 mg (FR)
LIBEO VET (DK, FI, SE)
Furosemide

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One tablet of 1320 mg contains :
Active substance:
Furosemide .....40 mg
Chewable tablet
Clover shape beige tablet. The tablets can be divided into equal quarters

4. INDICATION(S)

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. 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.
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).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

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 PERIOD(S)

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 WARNING(S)

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.

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.

Overdose (symptoms, emergency procedures, antidotes)
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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Local representative:

Approved: 05 December 2018