ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Libeo 40 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains :
Active substance:
Furosemide.....40 mg

Excipients:

Qualitative composition of excipients and other constituents
Chicken flavour
Yeast extract (Saccharomyces cerevisiae)
Maltodextrin
Magnesium stearate
Silica, colloidal anhydrous
Microcrystalline cellulose
Sodium croscarmellose
Lactose monohydrate

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

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

3.3 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 to any of the excipients.

3.4 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.

3.5 Special precautions for use

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:
Not applicable.

3.6 Adverse events

Dogs

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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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.

3.9 Administration routes and dosage

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	¼
10.1-12.5 kg	Use Libeo 10 mg
12.6 – 15 kg	Use Libeo 10 mg
15.1 – 20 kg	½
20.1 – 30 kg	¾
30.1 – 40 kg	1
40.1 – 50 kg	1 ¼

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
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures, and 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.

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC Vet Code:QC03CA01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

Not applicable.

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{mm/yyyy}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A.LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Libeo 40 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains :
Active substance:
Furosemide ..... 40 mg

3. PACKAGE SIZE

8 tablets
16 tablets
96 tablets
120 tablets
200 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

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

14. MARKETING AUTHORISATION NUMBER(S)

15. MANUFACTURER'S BATCH NUMBER

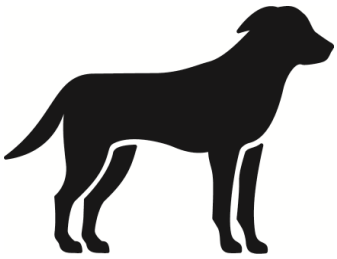
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Libeo



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

Furosemide 40 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Libeo 40 mg chewable tablets for dogs

2. Composition

Each tablet 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

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.

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

Dogs:

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.

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

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20.1 – 30 kg	¾
30.1 – 40 kg	1
40.1 – 50 kg	1 ¼

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 or household waste.
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 or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorization numbers and pack sizes

(MA)

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. Date on which the package leaflet was last revised

{mm/yyyy}
Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contacts details to report suspected adverse reactions:
(Name and address to be completed nationally)
Tel: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 LOUVERNE
France

17. Other information