SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frusemide 40 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Qualitative composition	Quantitative composition
Furosemide (Frusemide)	40 mg per tablet

Excipients

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.
White, circular, biconvex, flat-faced tablets with bevelled edges, with F40 on one side and CP or DP on the reverse, and a breakline.

4. CLINICAL PARTICULARS

4.1 Target species

Cats and dogs.

4.2 Indications for use, specifying the target species

For the treatment of oedema associated with cardiac insufficiency, renal dysfunction and trauma in cats and dogs.
In animals with pulmonary oedema of cardiac origin, combined therapy with other medicinal products may be indicated.

4.3 Contraindications

Do not use in animals with acute glomerular nephritis, renal failure with anuria, electrolyte deficiency disease or in animals that have received an overdosage of digitalis.
Do not use concurrently with aminoglycoside antibiotics.
Do not use in animals weighing less than 4 kg.

4.4 Special warnings for each target species

There are no special warnings required for either target species.

4.5 Special precautions for use

i. Special precautions for use in animals

Do not exceed the recommended dosage.
Therapeutic efficacy may be impaired by increased intake of drinking water. Where the animal's condition permits, water intake should be restricted during treatment with Frusemide 40 mg tablets.

Monitoring of plasma potassium levels is advisable during periods of prolonged treatment of combined therapy with cardiac glycosides. Potassium supplements may be necessary.

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

Wear gloves, or wash your hands immediately after handling the tablets.

4.6 Adverse reactions (frequency and seriousness)

During the post-authorisation period and following use of the product in dogs displaying signs of cardiac disease, lethargy, malaise and a fast or irregular heartbeat have been recorded rarely.
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.

4.7 Use during pregnancy, lactation or lay

Frusemide 40 mg tablets are not contraindicated in pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration with corticosteroids may increase the risk of hypokalaemia.
Concurrent administration with aminoglycoside antibiotics may result in ototoxicity.
Concurrent administration with cephalosporin antibiotics may result in nephrotoxicity.
Concurrent administration with digoxin enhances the cardiac glycoside.
Concurrent administration with sulphonamide antibacterials may result in sulphonamide allergy.

4.9 Amounts to be administered and administration route

For oral administration only.
Cats and dogs:
Dosage up to 5 mg/kg bodyweight, or one tablet, per 8 kg bodyweight, one to two times daily with an interval of 6 - 8 hours between administrations.

For animals weighing between 4 and 8 kg, one half of one tablet should be administered. The tablets may be divided by breaking along the score line.
For maintenance, the dosage should be reduced to 1 - 2 mg/kg per day.
Not to be used in animals under 4 kg bodyweight.

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

Transitory deafness may occur in animals administered the product at doses higher than those recommended.
Cardiovascular side effects may occur in weak and old animals following overdosage.
Excessive doses can lead to hypovolaemia and decompensate renal function.
Management of signs of overdosage is symptomatic.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PARTICULARS

Pharmacotherapeutic group: Furosemide

ATC Vet Code: QC03CA01

5.1 Pharmacodynamic properties

The tablets contain Furosemide. Furosemide is a potent loop diuretic with a rapid action.

5.2 Pharmacokinetic properties

Furosemide inhibits electrolyte resorption in the proximal and distal renal tubules and in the ascending Loop of Henle. Excretion of sodium, potassium and chloride ions is enhanced, and also water excretion is enhanced. Furosemide has no effect on carbonic anhydrase. Diuretic activity begins one hour after oral administration and continues for four hours. The potency ensures diuretic action even when renal function is poor. Loop diuretics may cause severe potassium loss.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Pregelatinised starch
Magnesium stearate
Lactose monohydrate
Water, purified

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

White polypropylene containers with low density polyethylene, push fit, tamper evident caps, containing 250 or 1000 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 10434/4059

9. DATE OF FIRST AUTHORISATION

21 May 2003

10. DATE OF REVISION OF THE TEXT

March 2022

Approved 03 March 2022