SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frusedale 40 mg Oral Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active ingredient

Furosemide (Frusemide)	40 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.
White, circular, biconvex, flat-faced tablets with bevelled edges 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

None.

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 Frusedale 40 mg oral 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.

iii. Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Administration at the recommended dosage level is not normally associated with undesirable effects.

4.7 Use during pregnancy, lactation or lay

Frusedale 40 mg oral 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 Frusedale 40 mg oral tablet, per 8 kg bodyweight, one to two times daily with an interval of 6 - 8 hours between administrations.

For maintenance, the dosage should be reduced to 1 - 2 mg/kg per day.

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.

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

Frusedale 40 mg oral 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 maize starch
Magnesium stearate
Lactose monohydrate

6.2 Incompatibilities

There are no known incompatibilities.

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 contents of immediate packaging

Polypropylene containers containing 1000 white, circular, biconvex, flat-faced tablets with bevelled edges, a breakline and which are embossed F40 on one face, CP or DP on the reverse.

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
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Jamage Industrial Estate
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ST7 1XW
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8. MARKETING AUTHORISATION NUMBER

Vm 10434/4033

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14/08/1998
Date of renewal of the authorisation: 14/08/2003

10. DATE OF REVISION OF THE TEXT

March 2011