PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frusedale 40
40 mg oral tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:
Frusemide/Furosemide 40 mg

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

1000 tablets

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For oral administration only.
Cats and dogs: Dosage up to 5 mg/kg body weight, or one tablet per 8 kg body weight, 1-2 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 body weight.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

For animal treatment only.
See the package leaflet for full details.
Wash hands after use.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

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

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

Prescription Only Medicine – Veterinarian

To be supplied only on veterinary prescription.
UK authorised veterinary medicinal product.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10434/4033

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

Frusedale 40
40 mg oral tablets

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frusedale 40
40 mg oral tablets
1000 tablets

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

White, circular, biconvex, flat-faced tablets with bevelled edges and a breakline.
Each tablet contains frusemide/furosemide 40 mg.

4. INDICATION(S)

Frusedale 40 mg oral tablets are for use in cats and dogs only, for the treatment of oedema associated with cardiac insufficiency, renal dysfunction and trauma.
In animals with pulmonary oedema of cardiac origin, combined therapy with other medicinal products may be indicated.
Frusemide is a potent diuretic with an onset of activity normally within 1 hour of administration and a duration of activity of approximately 4 hours.

5. CONTRAINDICATIONS

Do not use in animals weighing less than 4 kg.
Do not use in animals with 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 or corticosteroids.
Concurrent administration with aminoglycoside antibiotics may result in ototoxicity.
Concurrent use of corticosteroids may increase the risk of hypokalaemia.
Concurrent administration with cephalosporin antibiotics may result in nephrotoxicity.
Concurrent administration with sulphonamide antibacterials may result in sulphonamide allergy.

6. ADVERSE REACTIONS

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.

7. TARGET SPECIES

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

For oral administration only.
Cats and dogs above 4 kg body weight:
Dosage up to 5 mg/kg body weight, or one Frusedale 40 mg oral tablet per 8 kg body weight, 1 to 2 times daily with an interval of 6 to 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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

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

12. SPECIAL WARNINGS

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.
Frusedale 40 mg oral tablets may be used in pregnant or lactating animals.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

User Warnings

Wear gloves or wash hands immediately after handling the tablets.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2022

15. OTHER INFORMATION

For animal treatment only.

POM-V	Prescription Only Medicine – Veterinarian

To be supplied only on veterinary prescription.
UK authorised veterinary medicinal product.

Vm 10434/4033

Package quantity: Plastic containers of 1000 tablets.

Keep out of the sight and reach of children.

Do not use after the expiry date stated on the label.

For information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, UK

Approved 03 March 2022