PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frusemide
40 mg Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains Furosemide (Frusemide) 40 mg.

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

1000 tablets.

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration to cats and dogs above 4 kg bodyweight only.

One tablet per 8 kg body weight.
The tablets are scored; one half of one tablet should be given to animals weighing between 4 and 8 kg.
Frusemide 40 mg tablets should be administered 1 – 2 times daily, with an interval of 6 – 8 hours between administrations.
See package leaflet for further details.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings

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

10. EXPIRY DATE

Do not use after stated 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

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

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

For animal treatment only.

POM-V

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 10434/4059

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

Frusemide
40 mg Tablets

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frusemide
40 mg Tablets

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

White, circular, biconvex, flat-faced tablets with bevelled edges and a breakline, embossed F40 on one face and CP or DP on the reverse. Each tablet contains Furosemide/Frusemide 40 mg.

4. INDICATION(S)

Frusemide 40 mg 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.
Furosemide 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 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 or corticosteroids.
Do not use in animals weighing less than 4 kg.
Concurrent administration with aminoglycoside antibiotics may result in ototoxicity.
Concurrent administration with cephalosporin antibiotics may result in nephrotoxicity.
Concurrent administration with sulphonamide antibacterials may result in sulphonamide allergy.

Concurrent use of corticosteroids may increase the risk of hypokalaemia.

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(S) AND METHOD OF ADMINISTRATION

For oral administration to cats and dogs above 4 kg body weight only:
One Frusemide 40 mg tablet per 8 kg body weight administered 1 or 2 times per day, with an interval of 6 to 8 hours between doses.
Each tablet is scored to facilitate division:
One half of one tablet should be administered to animals weighing between 4 kg and 8 kg.
Do not exceed the recommended dose.
For maintenance, the dosage should be reduced to 1 to 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 WARNING(S)

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.
Frusemide 40 mg 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, IF ANY

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

Keep out of the sight and reach of children.

For animal treatment only.

POM-V	Prescription Only Medicine – Veterinarian

To be supplied only on veterinary prescription.

UK authorised veterinary medicinal product.

Vm 10434/4059

Package quantities: Plastic containers of 250 or 1000 tablets. Not all pack sizes may be marketed.

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

Approved 03 March 2022