PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – LABEL AND BASE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frusecare Tablets 40 mg Frusemide (Furosemide) 40 mg

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

User Warnings

Wash hands after use.

For full details of dosage and administration, contraindications and warnings, see the package leaflet attached.

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]

For animals 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 reach and site of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10434/4066

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

4. INDICATION(S)

Frusecare 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 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 use of 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 sulphonamide antibacterials may result in sulphonamide allergy.

6. ADVERSE REACTIONS

7. TARGET SPECIES

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

For oral administration only.

Dogs and cats above 4 kg body weight:

Dosage up to 5 mg/kg body weight, or one Frusecare 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 1-2 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 Frusecare tablets.

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

Frusecare 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

15. OTHER INFORMATION

Keep out of the reach and site of children.

For animals treatment only.

POM-V Prescription Only Medicine – Veterinarian

To be supplied only on veterinary prescription.

Vm 10434/4066

Package quantities: Plastic containers of 1000 tablets.

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

Approved: 03/08/2017 Flory