

Frusedale[®] 40

40 mg oral tablets 1000 tablets

UK

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

Name of the veterinary medicinal product:

Frusedale[®] 40
40 mg oral tablets
1000 tablets

Presentation:

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

Statement of the active substance and other ingredients:

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

Indications:

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.

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.

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.

Special storage precautions:

Keep out of the sight and reach of children.
Do not store above 25°C. Protect from light.
Do not use after the expiry date stated on the label.

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 your hands immediately after handling the tablets.

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.

Date on which the package leaflet was last approved:

September 2017

Other information:

For animal treatment only.
To be supplied only on veterinary prescription.
Vm 10434/4033
POM-V Prescription Only Medicine - Veterinarian
UK authorised veterinary medicinal product.
Package quantity: Plastic containers of 1000 tablets.

Marketing authorisation holder:

Dechra Limited, Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, UK.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
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