SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Furosivet 20 mg tablets for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Furosemide 20 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
White circular, flat faced tablet with bevelled edges. Embossed F20 with break-line on one face and plain on reverse.
The tablets can be divided into two equal parts.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats

4.2 Indications for use, specifying the target species

For the treatment of oedema and ascites, particularly resulting from cardiac insufficiency, renal dysfunction, or of a traumatic origin.

4.3 Contraindications

Do not use in acute glomerular nephritis.
Do not use in patients that have received excessive doses of cardiac glycosides.
Do not use in combination with other loop diuretics.
Do not use the product in animals suffering from hypovolaemia, hypotension or dehydration.
Do not use in cases of renal failure with anuria.
Do not use in cases of electrolyte deficiency.
Do not use in cases of known hypersensitivity to furosemide, sulphonamides or any of the excipients.

4.4 Special warnings for each target species

The patient may increase its water intake to compensate for the diuresis. Consideration should be given to restricting water intake to physiologically normal amounts, if the patient's condition makes such a course appropriate.

4.5 Special precautions for use

Special precautions for use in animals

Furosemide should be used with caution in case of pre-existing electrolyte and/or water imbalance, impaired hepatic function (may precipitate hepatic coma) and diabetes mellitus. In case of prolonged treatment, hydration status and serum electrolytes should be monitored frequently. Prolonged dosage may on occasions justify potassium supplementation, especially if the product is used in conjunction with cardiac glycosides.
1-2 days before and after commencement of treatment with diuretics and ACE inhibitors renal function and hydration status should be monitored.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Furosemide has possible genotoxic properties and there is evidence of carcinogenicity in mice. Although there is inconclusive evidence relating to these effects in humans, skin contact with or accidental ingestion of the product should be avoided. Wear impervious gloves during handling and administration of the product and wash hands thoroughly afterwards.
For the same reasons, the product is supplied in a container with a child-resistant closure. The cap of the container must be securely engaged after use. If smaller quantities are dispensed from the pack, they must be supplied in a container with a child-resistant closure. If appropriate containers are not available, the product must be supplied in the original container.
Unused tablets or half tablets should be placed back into the container, the child-resistant closure replaced, and the product stored safely, out of the sight and reach of children.
In case of accidental ingestion seek medical attention and show product label and/or pack insert to the doctor.
People with known hypersensitivity to furosemide should avoid contact with the veterinary medicinal product.
Do not handle this product if you know you are sensitive to sulphonamides as hypersensitivity to sulphonamides may lead to hypersensitivity to furosemide.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Due to the diuretic action of furosemide, there may be haemoconcentration and impairment of the circulation. In cases of prolonged treatment electrolyte deficiency (including hypokalaemia, hyponatraemia) and dehydration may occur.

4.7 Use during pregnancy, lactation or lay

Laboratory studies have shown evidence of teratogenic effects.
The safety of the veterinary medicinal product in the target species has not been established during pregnancy or lactation.
Use only according to the benefit-risk assessment by the responsible veterinarian.
A deleterious effect on lactation is to be expected, particularly if drinking water is restricted. Furosemide passes into milk, but not to a great extent.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent use with drugs affecting electrolyte balance (corticosteroids, other diuretics, amphotericin B, cardiac glycosides) requires careful monitoring.
Furosemide may increase the risk of sulphonamide allergy.
Furosemide may alter insulin requirements in diabetic animals.
Furosemide may reduce the excretion of NSAIDs.
The dose regimen may need to be modified for long term treatment in combination with ACE inhibitors, depending upon the animal's response to therapy.
Concomitant use with aminoglycosides or cephalosporins may increase the risk of nephrotoxicity.

4.9 Amounts to be administered and administration route

Oral route
The initial dosage is 5 mg furosemide per kg bodyweight per day, given in a single dose or in two divided daily doses. This corresponds to 1 tablet per 4 kg bodyweight per day or ½ tablet per 4 kg bodyweight twice a day. Depending on the severity of the oedema or ascites or in refractory cases, the initial daily dosage may be doubled.
For maintenance, daily dosage should be adapted to the lowest effective dose by the veterinarian depending on the clinical response of the dog/cat to the therapy.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Dehydration and electrolyte depletion may occur. Monitor and correct as necessary.
Dosage higher than that which is recommended, may cause transitory deafness and CNS effects (lethargy, coma, seizures). Cardiovascular side effects (e.g. hypotension, heart rhythm disorders, collapse) may be observed in weak and old patients following overdose.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: diuretics, furosemide.
ATC vet code: QC03CA01

5.1 Pharmacodynamic properties

Furosemide is a potent loop diuretic that increases urinary volume. It inhibits electrolyte resorption in the proximal and distal renal tubules and in the ascending Loop of Henle. Excretion of sodium ions, chloride ions and to a lesser extent, potassium ions is enhanced, as is water excretion. Furosemide has no effect on carbonic anhydrase.

5.2 Pharmacokinetic particulars

Furosemide is incompletely but fairly rapidly absorbed from the gastrointestinal tract. It has a biphasic half-life in the plasma with a terminal elimination phase that has been estimated to range up to about 1.5 hours. Furosemide is mainly excreted in the urine. Furosemide crosses the placental barrier and is excreted in milk. Metabolism of furosemide is very limited.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Pregelatinised starch
Magnesium stearate

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years

6.4 Special precautions for storage

Store in the original container in order to protect from light and moisture. The silica gel bag should be kept inside the container. Half tablets should be replaced back into the original container and should be given at the next administration.

6.5 Nature and composition of immediate packaging

White ,high-density polyethylene container containing 250 tablets, with a silica gel bag desiccant, and sealed with a white, child-resistant, polypropylene closure.

Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 12, 15, 25 or 50 Aluminium-PVC foil/PVC-PVDC blisters of 10 tablets each corresponding to 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 150, 250 or 500 tablets per box.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Millpledge Ltd
Whinleys Estate
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DN22 9NA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 04409/4007

9. DATE OF FIRST AUTHORISATION

05 March 2019

10. DATE OF REVISION OF THE TEXT

May 2024

Approved: 13 May 2024