Upcard

Species: Dogs
Therapeutic indication:**Pharmaceuticals:** Diuretics
Active ingredient: Torasemide
Product: UpCard 0.75/3.0/7.5 mg tablets for dogs
Product index: Upcard tablets for dogs

Presentation

UpCard 0.75 mg tablets: oblong white to off-white tablets with 1 break-line on each side. The tablets can be divided into equal halves.

UpCard 3 mg and 7.5 mg tablets: oblong white to off-white tablets with 3 break-lines on each side. The tablets can be divided into equal quarters.

Uses

For treatment of clinical signs, including oedema and effusion, related to congestive heart failure.

Dosage and administration

Oral use.

UpCard tablets can be administered with or without food.

The recommended dose of torasemide is 0.1 to 0.6 mg per kg bodyweight, once daily. The majority of dogs are stabilised at a dose of torasemide less than or equal to 0.3 mg per kg bodyweight, once daily. The dosage should be titrated to maintain patient comfort with attention to renal function and electrolytes status. If the level of diuresis requires alteration, the dose may be increased or decreased within the recommended dose range by increments of 0.1 mg/kg bodyweight. Once signs of congestive heart failure have been controlled and the patient is stable, if long term diuretic therapy with this product is required it should be continued at the lowest effective dose.

Frequent re-examinations of the dog will enhance the establishment of an appropriate diuretic dose.

The daily schedule of administration can be timed to control the period of micturition according to need.

Contra-indications, warnings, etc

Do not use in case of renal failure.

Do not use in case of severe dehydration, hypovolaemia or hypotension.

Do not use concomitantly with other loop diuretics.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Special precautions for use in animals

In dogs presenting in acute crisis with pulmonary oedema, pleural effusion and/or ascites requiring emergency treatment, the use of injectable drugs should be considered first before commencing oral diuretic therapy.

Renal function, hydration status and serum electrolytes status should be monitored:

- At treatment initiation

- from 24 hours to 48 hours after treatment initiation

- from 24 hours to 48 hours after dose change

- In case of adverse events.

While the animal is on treatment, these parameters should be monitored at very regular intervals according to the benefit-risk assessment performed by the responsible veterinarian.

Torasemide should be used with caution in cases of diabetes mellitus, and in dogs with previously prescribed high doses of an alternative loop diuretic. In dogs with pre-existing electrolyte and/or water imbalance, this should be corrected prior to treatment with torasemide.

Torasemide treatment should not be initiated in dogs already clinically stable on an alternative diuretic for treatment of the signs of congestive heart failure, except where this has been justified taking into account the risk of de-stabilising the clinical condition and of adverse reactions as indicated below.

Operator warnings

People with known hypersensitivity to torasemide or other sulphonamides should administer the veterinary medicinal product with caution.

This product may cause increased urination and/or gastrointestinal disturbances if ingested.

Keep tablets in the blister packs until required, and keep the blisters in the outer carton.

In case of accidental ingestion, particularly in the case of children, seek medical advice immediately and show the package leaflet or the label to the physician.

Adverse reactions (frequency and seriousness)

Increase in renal blood parameters and renal insufficiency are very commonly observed during treatment.

As a result of the diuretic action of torasemide, haemoconcentration and, very commonly,

polyuria and/or polydipsia are observed.

In cases of prolonged treatment, electrolyte deficiency (including hypokalaemia, hypochloraemia, hypomagnesaemia) and dehydration may occur.

Gastrointestinal signs which include emesis, reduced or absent faeces and, in rare cases, soft faeces may be observed. Occurrence of soft faeces is transient, mild, and does not necessitate the withdrawal of the treatment.

Erythema of the inner pinnae may be observed.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)

- common (more than 1 but less than 10 animals in 100 animals)

- uncommon (more than 1 but less than 10 animals in 1,000 animals)

- rare (more than 1 but less than 10 animals in 10,000 animals)

- very rare (less than 1 animal in 10,000 animals, including isolated reports).

Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. The use of UpCard is not recommended during pregnancy, lactation and in breeding animals.

Interaction with other medicinal products and other forms of interaction

Co-administration of loop diuretics and NSAIDs can result in a decreased natriuretic response.

Concomitant use with veterinary medicinal products affecting electrolyte balance (corticosteroids, amphotericin B, cardiac glycosides, other diuretics) requires careful monitoring.

Concurrent use of drugs that increase the risk of renal injury or renal insufficiency should be avoided.

Concomitant use with aminoglycosides or cephalosporins may increase the risk of nephrotoxicity and ototoxicity.

Torasemide may increase the risk of sulfonamide allergy.

Torasemide can reduce the renal excretion of salicylates, leading to an increased risk of toxicity.

Care should be exercised when administering torasemide with other highly plasma protein bound drugs. Since protein binding facilitates the renal secretion of torasemide, a decrease in binding due to displacement by another drug may be a cause of diuretic resistance.

Concomitant administration of torasemide with other drugs metabolised by cytochrome P450 families 3A4 (e.g.: enalapril, buprenorphine, doxycycline, cyclosporine) and 2E1 (isoflurane, sevoflurane, theophylline) may decrease their clearance from the systemic

circulation.

The effect of antihypertensive drugs, especially angiotensin converting enzyme (ACE)-inhibitors, may be potentiated when co-administered with torasemide.

When used in combination with cardiac treatments (e.g. ACE-inhibitors, digoxin), the dose regimen may need to be modified depending upon the animal's response to therapy.

Adverse reactions (frequency and seriousness)

Doses greater than 0.8 mg/kg/day have not been evaluated in the target animal safety or controlled clinical studies. However, it is anticipated that overdose increases the risk of dehydration, electrolyte imbalance, renal insufficiency, anorexia, weight loss and cardiovascular collapse.

Treatment should be symptomatic.

Pharmaceutical precautions

Any remaining tablet part should be discarded after 7 days.

This veterinary medicinal product does not require any special storage conditions.

Any part tablet should be stored in the blister pack or in a closed container for a maximum of 7 days.

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

Legal category

Legal category:POM-V

Packaging quantities

Blister pack containing 10 tablets

All strengths are available in the following pack sizes:

Pack sizes of 30 or 100 tablets.

Not all pack sizes may be marketed.

Further information

Pharmacokinetic particulars

In dogs, after a single intravenous dose at 0.1 mg/kg, the total body clearance was 0.017

L/h·kg, the volume of distribution was 0.14 L/kg and the terminal half-life was 7.0 hours. After a single oral dose of 0.1 mg/kg, the oral absolute bioavailability corresponded to about 90%. The oral absorption was fast with mean Tmax at 0.93 hours after administration of 0.1 mg/kg. The maximum plasma concentrations Cmax corresponded to 1.1 µg/mL after a single oral dose of 0.1 mg/kg and to 19 µg/mL after a single oral dose of 1.6 mg/kg. The AUCinf corresponded to 6.3 µg·h/mL after a single oral dose of 0.1mg/kg and to 153.6 µg·h/mL after a single oral dose of 1.6 mg/kg. The plasma protein binding was > 98%. A large proportion of the dose (between 61% and 70%) is excreted in the urine as unchanged parent drug. Two metabolites (a dealkylated and a hydroxylated metabolite) were also identified in urine. The parent drug is metabolised by the hepatic cytochrome P450 families 3A4 and 2E1, and to a lesser extent by 2C9. Dose proportionality for Cmax and AUCinf was demonstrated between 0.2 and 1.6 mg/kg. Feeding significantly increased torasemide AUClast by 36% on average and slightly delayed Tmax but no significant impact on Cmax was detected. After repeated administration to dogs at 0.2 mg/kg daily for 14 days, no plasma accumulation of torasemide was detected.

Marketing Authorisation Holder (if different from distributor)

Vetoquinol SA

Magny-Vernois

Lure 70200

FRANCE

Marketing Authorisation Number

EU/2/15/184/001–008

Significant changes

GTIN

GTIN description: Upcard 0.75 mg 30 tablets
GTIN:03605874403758
GTIN description: Upcard 0.75 mg 100 tablets
GTIN:03605874403802
GTIN description: Upcard 3.0 mg 30 tablets
GTIN:03605874403857
GTIN description: Upcard 3.0 mg 100 tablets
GTIN:03605984403901
GTIN description: Upcard 7.5 mg 100 tablets
GTIN:03605874420892

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