PARTICULARS TO APPEAR ON THE OUTER PACKAGE - Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UpCard 3 mg tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

3 mg of torasemide

3. PACKAGE SIZE

30 tablets
100 tablets

4. TARGET SPECIES

Dogs.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol SA

14. MARKETING AUTHORISATION NUMBERS

Vm 06462/5014

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS - Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UpCard 3 mg tablets for dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

3 mg of torasemide

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

UpCard 0.75 mg tablets for dogs
UpCard 3 mg tablets for dogs
UpCard 7.5 mg tablets for dogs
UpCard 18 mg tablets for dogs

2. Composition

Each tablet contains:

Active substance:

UpCard 0.75 mg tablets for dogs	0.75 mg of torasemide
UpCard 3 mg tablets for dogs	3 mg of torasemide
UpCard 7.5 mg tablets for dogs	7.5 mg of torasemide
UpCard 18 mg tablets for dogs	18 mg of torasemide

UpCard 0.75 mg tablets are oblong white to off-white tablets with 1 break-line on each side. The tablets can be divided into equal halves.
UpCard 3 mg, 7.5 mg and 18 mg tablets are oblong white to off-white tablets with 3 break-lines on each side. The tablets can be divided into equal quarters.

3. Target species

Dogs.

4. Indications for use

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

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of renal failure.

Do not use in cases of severe dehydration, hypovolaemia or hypotension.
Do not use concomitantly with other loop diuretics.

6. SPECIAL WARNING(S)

Special precautions for safe use in the target species:
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
- 24 hours to 48 hours after treatment initiation
- 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 (see contraindications and adverse reactions sections).

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 in section 6.

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

Pregnancy and lactation:
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 non-steroidal anti-inflammatory drugs (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 veterinary medicinal products 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 veterinary medicinal products metabolised by cytochrome P450 isoforms such as 3A4 (e.g. enalapril, buprenorphine, doxycycline, cyclosporine) and 2E1 (isoflurane, sevoflurane, theophylline) may decrease their clearance from the systemic circulation.

The effect of antihypertensive medicinal products, 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.

Overdose
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.

Major incompatibilities:

Not applicable.

7. Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Elevated renal parameters, Renal insufficiency Haemoconcentration, Polyuria, Polydipsia
Common (1 to 10 animals / 100 animals treated):	
Uncommon (1 to 10 animals / 1,000 animals treated):	
Rare (1 to 10 animals / 10,000 animals treated):	
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypokalaemia*[1], Hypochloraemia*[1], Hypomagnesaemic condition *[1] Dehydration Vomiting, Constipation, Reduced faecal output, Soft stool*[2] Pinnal erythema

*[1]: In cases of prolonged treatment

*[2]: Transient, mild, and does not necessitate the withdrawal of the treatment

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use.

The recommended dose of torasemide is 0.1 to 0.6 mg per kg bodyweight, once daily. The dosage should be titrated to maintain patient comfort with attention to

renal function and electrolyte 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-examination 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.

9. ADVICE ON CORRECT ADMINISTRATION

This veterinary medicinal product can be administered with or without food.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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. Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the blister after Exp. The expiry dates refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

POM-V (Veterinary medicinal product subject to prescription)

14. Marketing authorisation numbers and pack sizes

Vm 06462/5012 0.75mg
Vm 06462/5014 3mg
Vm 06462/5015 7.5mg
Vm 06462/5013 18mg

UpCard tablets are supplied in blister packs with 10 tablets per blister pack. Pack sizes are of 30 or 100 tablets.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Vetoquinol SA
34 Rue de Chene Sainte-Anne
Magny-Vernois
70200 Lure
France

Local representatives and contact details to report suspected adverse reactions:

United Kingdom (Great Britain)
Vetoquinol UK Ltd
Tel: +441 280 814 500

17. Other information

Based on a pharmacodynamics modelling study conducted in healthy dogs at doses of 0.1 and 0.6 mg torasemide/kg, a single dose of torasemide had approximately 20 times the diuretic effect of a single dose of furosemide.

POM-V

For animal treatment only.

Gavin Hall

Approved: 11 February 2025