

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benamix 6.25 mg/g premix for medicated feeding stuff

2. STATEMENT OF ACTIVE SUBSTANCES

Benazepril hydrochloride 6.25 mg/g

3. PACKAGE SIZE

5 L plastic barrel containing 4.23 L (or 4.032 kg)

4. TARGET SPECIES

Cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In-feed use.

Only to be mixed into dry feed by a feed business operator.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use immediately.

Once mixed into the feed: use within 12 months.

9. SPECIAL STORAGE PRECAUTIONS

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

VIRBAC

14. MARKETING AUTHORISATION NUMBER

Vm 05653/3033

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Benamix 6.25 mg/g premix for medicated feeding stuff for cats.

2. Composition

Each g contains:

Active substance:

Benazepril hydrochloride	6.25 mg
equivalent to Benazepril	5.76 mg

Excipients:

Butylhydroxyanisole (E320)	0.2 mg
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White to yellow suspension.

3. Target species

Cats.

4. Indications for use

Reduction of proteinuria associated with chronic kidney disease.

5. Contraindications

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

Do not use in case of hypotension, hypovolaemia, hyponatraemia, or acute renal failure.

Do not use in case of cardiac output failure due to aortic or pulmonary stenosis.

Do not use during pregnancy or lactation.

6. Special warnings

Special warnings:

The uptake of the medicated feed can be altered as a consequence of CKD or other diseases and should be monitored. In case of insufficient feed intake, i.e less than 50% of the prescribed feed intake for more than 7 consecutive days, the efficacy of the treatment cannot be guaranteed and the animal should be presented to a veterinarian in order to investigate the cause of this diminished feed intake and apply the suitable treatment. Cats suffering from anorexia or inappetence should not be treated via medicated feed.

To ensure a better acceptance of the new feed and to avoid digestive issues, a feed transition may be implemented over some days at the discretion of the veterinarian.

Special precautions for safe use in the target species:

If more than one cat is living in the household, ensure that only the cat for which this treatment is prescribed has access to the medicated feed, and that the cat being treated receives the appropriate dose (i.e., amount of medicated feed).

No evidence of renal toxicity of Benazepril has been observed during clinical trials, however, as is routine in cases of chronic kidney disease, it is recommended to monitor plasma creatinine, urea and erythrocyte counts during therapy. The efficacy and safety of the veterinary medicinal product has not been established in cats below 2.5 kg body weight.

The use of a Renin-Angiotensin-Aldosterone System (RAAS) inhibitor is not recommended in any cat that is clinically dehydrated or is showing signs of hypovolemia. Check and correct dehydration before using these drugs, otherwise glomerular filtration rate may drop precipitously if these drugs are introduced before the patient is adequately hydrated.

Precautions to be taken by the person administering the medicated feed to animals:

The medicated feed may be harmful when ingested by children.

Avoid accidental ingestion. The medicated feed and the feed bowl should be placed out of the reach and sight of children. In case of accidental oral ingestion, seek medical advice immediately and show the label of the medicated feed to the physician.

Angiotensin converting enzyme (ACE) inhibitors have shown to affect the foetus. Pregnant women, and women of childbearing potential, should take special care to avoid any skin exposure with the medicated feed, including oral exposure due to hand-to-mouth contact.

In case of accidental skin exposure or accidental ingestion, wash or rinse thoroughly and immediately with water, seek medical advice and show the label of the medicated feed to the physician.

Angiotensin converting enzyme (ACE) may cause hypersensitivity reactions.

People with known hypersensitivity to benazepril should avoid contact.

In case of hypersensitivity reactions, seek medical advice and show the label of the medicated feed to the physician.

Wash hands after use.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during breeding, pregnancy and lactation.

Benazepril reduced ovary/oviduct weights in cats when administered daily at the overdose of 10 mg/kg body weight for 52 weeks. Embryotoxic effects (foetal urinary tract malformation) were seen in trials with laboratory animals (rats) at maternally non toxic doses.

Do not use during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:

In humans, the combination of ACE inhibitors and non-steroidal anti-inflammatory drugs (NSAIDs) can lead to reduced anti-hypertensive efficacy or impaired renal function. The combination of the veterinary medicinal product and other anti-hypertensive agents (e.g. calcium channel blockers, β -blockers or diuretics), anaesthetics or sedatives may lead to additive hypotensive effects. Therefore, concurrent use of NSAIDs, telmisartan or other medications with a hypotensive effect should be considered with care. Renal function and signs of hypotension (lethargy, weakness etc) should be monitored closely and treated as necessary.

Interactions with potassium preserving diuretics like spironolactone, triamterene or amiloride cannot be ruled out. It is recommended to monitor plasma potassium levels when using the veterinary medicinal product in combination with a potassium sparing diuretic because of the risk of hyperkalaemia.

Overdose:

Benazepril reduced erythrocyte counts in normal cats when dosed at 10 mg/kg body weight once daily for 12 months, but this effect was not observed at the recommended dose during clinical trials in cats. Transient reversible hypotension may occur in cases of accidental overdose. Therapy should consist of intravenous infusion of warm isotonic saline.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea, Emesis Anorexia, Dehydration, Lethargy
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Elevated creatinine ¹ Increased appetite, Weight gain

¹In cats with chronic kidney disease, the veterinary medicinal product may increase plasma creatinine concentrations at the start of therapy. A moderate increase in plasma creatinine concentrations following administration of ACE inhibitors is compatible with the reduction in glomerular hypertension induced by these agents and is therefore not necessarily a reason to stop therapy in the absence of other signs.

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

In-feed use.

Only to be mixed into dry feed by a feed business operator.

The veterinary medicinal product is a premix intended for the manufacture of medicated feeding stuff. Do not administer the veterinary medicinal product other than mixed with feed by an authorized manufacturer of medicated feed.

Mixing instructions:

The barrel should be shaken about 20 seconds before use.

The incorporation process should consist in the incorporation of the whole barrel through simple mixing steps performed under normal conditions of temperature. The premix should be incorporated only by a coating process at the coating stage of the kibbles. An appropriate amount of fat and a palatable agent for cats should be incorporated in the external coating of the kibble. The premix should not be incorporated in the feed during the extrusion of the kibbles or by another process than coating.

To ensure the shelf-life of 12 months after incorporation in the feed, it is recommended that the medicated feed be filled into a bag with an aluminized layer and an internal polyethylene PE layer, and stored at a temperature not above 25°C.

The veterinary medicinal product should be administered orally after incorporation in feed in order to achieve a minimum dose of 0.5 mg (range 0.5 - 1.0) benazepril hydrochloride/kg body weight per day. In order to obtain the correct dosage, the concentration of the premix in the medicated feed may need to be adjusted accordingly by the feed business operator, taking into account the metabolizable energy of the feed.

In case the veterinary medicinal product is mixed at an incorporation rate of 72mg of benazepril per kg feed into a feed appropriate for renal patients, with a metabolizable energy of 416 kcal/ 100g, the feeding recommendation table might read as follows:

Body Weight (kg)	Range of daily ration (g/day) depending on the body condition and the activity of the cat*
2.5 - 2.9	25 - 35

3.0 - 3.4	25 - 35
3.5 - 3.9	30 - 45
4.0 - 4.4	35 - 50
4.5 - 4.9	40 - 55
5.0 - 5.4	45 - 60
5.5 - 5.9	50 - 65
6.0 - 6.4	55 - 75
6.5 - 6.9	60 - 80
7.0 - 7.4	65 - 85
7.5 - 7.9	70 - 90
8.0 - 8.4	75 - 95
8.5 - 8.9	80 - 105
9.0 - 9.4	80 - 110
9.5 - 9.9	85 - 115
10.0 - 10.4	90 - 120

*for adult neutered indoor cat with optimal BW: recommended ration is 9 g/kg BW/day

9. Advice on correct administration

The veterinary medicinal product is a premix intended for the manufacture of medicated feeding stuff. Do not administer the veterinary medicinal product other than mixed with feed by an authorized manufacturer of medicated feed.

The veterinary medicinal product should be administered orally after incorporation in feed in order to achieve a minimum dose of 0.5 mg (range 0.5 - 1.0) benazepril hydrochloride/kg body weight per day.

The intake of medicated feed depends on the body weight, the activity and the body condition of the animal.

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.

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

Shelf life after first opening the immediate packaging: use immediately.
Shelf life of the medicated feed: 12 months

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 05653/3033

5 L plastic barrel containing 4.23L (or 4.032 kg)

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:

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Local representatives contact details to report suspected adverse reactions:

Virbac Ireland
McInerney & Saunders 38
Main Street, Swords
Co Dublin
K67 E0A2
Ireland
Tel: +44 (0)-1359 243243

17. Other information

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Approved 04 December 2025
Gavin Hall