

tablets for dogs

Name of the veterinary medicinal product

Fortekor Flavour 20 mg tablets for dogs

Composition

Each tablet contains 20 mg benazepril hydrochloride. Beige to light brown, ovaloid, divisible tablets, scored on both sides. The tablets can be divided into equal halves.

Target species

Dogs

Indications for use

The veterinary medicinal product belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors. It is prescribed by the veterinary surgeon for the treatment of congestive heart failure in dogs.

Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the

Do not use in cases of hypotension (low blood pressure), hypovolemia (low blood volume), hyponatraemia (low blood sodium levels) or acute renal failure. Do not use in cases of cardiac output failure due to aortic or pulmonary

Do not use in pregnant or lactating dogs because the safety of benazepril hydrochloride has not been established during pregnancy or lactation in

Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:

The efficacy and safety of the veterinary medicinal product has not been established in dogs below 2.5 kg body weight.

In cases of chronic kidney disease, your veterinarian will check the hydration status of your pet before starting therapy and may recommend that regular blood tests are carried out during therapy in order to monitor plasma creatinine concentrations, urea and blood erythrocyte counts.

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

ACE inhibitors have been found to affect the unborn child during pregnancy in humans. Pregnant women should take special care to avoid accidental oral exposure.

Wash hands after use.

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

Special precautions for the protection of the environment: Not applicable.

Pregnancy and lactation:

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

Do not use during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction: Inform the veterinary surgeon if the animal is taking, or has recently taken, any other medicines.

In dogs with congestive heart failure, the veterinary medicinal product has been given in combination with digoxin, diuretics, pimobendan and anti-arrhythmic products without evidence of associated adverse reactions.

In humans, the combination of ACE inhibitors and NSAIDs (non-steroidal antiinflammatory drugs) can lead to reduced anti-hypertensive efficacy or impaired kidney function. The combination of the 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 or other medications with a hypotensive effect should be considered with care. Your veterinary surgeon may recommend to closely monitor kidney function and for signs of hypotension (lethargy, weakness etc) and treat these if necessary.

Interactions with potassium-preserving diuretics like spironolactone, triamterene or amiloride cannot be ruled out. Your veterinary surgeon may recommend to monitor plasma potassium concentrations when using the veterinary medicinal product in combination with a potassium-sparing diuretic because of the risk of hyperkalaemia (high blood potassium).

Overdose:

Transient reversible hypotension (low blood pressure) may occur in cases of accidental overdose. Therapy should consist of intravenous infusion of warm isotonic saline.

Major incompatibilities:

Not applicable.

Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):
Diarrhoea, Vomiting, Anorexia, Fatigue
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Elevated creatinine ¹ , Incoordination

¹In dogs with chronic kidney disease, the 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.

Ireland

HPRA Pharmacovigilance Website: www.hpra.ie

United Kingdom (Northern Ireland)

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

reacts-medicine

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

Dosage for each species, routes and method of administration

Oral use.

This veterinary medicinal product should be given once daily, with or without food. The duration of treatment is unlimited.

This product is flavoured and is taken voluntarily by most dogs.

In dogs, this veterinary medicinal product should be administered at a minimum dose of 0.25 mg (range 0.25-0.5) benazepril hydrochloride/kg body weight once daily, according to the following table:

Weight of dog	20 mg tablet strength	
(kg)	Standard dose	Double dose
>20 - 40	0.5 tablet	1 tablet
>40 - 80	1 tablet	2 tablets

In dogs the dose may be doubled, still administered once daily, to a minimum dose of 0.5 mg (range 0.5-1.0) benazepril hydrochloride/kg body weight if judged necessary and advised by the veterinary surgeon. Always follow the dosing instructions given by the veterinary surgeon.

Advice on correct administration

For oral use only. Wash hands after use.

Withdrawal periods

Not applicable.

Special storage precautions

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

Each time an unused half tablet is stored, it should be returned to the open blister space, inserted back into the cardboard box and kept in a safe place out of the sight and reach of children.

Keep out of the sight and reach of children.

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

Shelf-life of tablet halves: 2 days.

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Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

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

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

Marketing authorisation numbers and pack sizes

14 tablets per aluminium/aluminium blister.

Cardboard box with:

1 blister (14 tablets)

2 blisters (28 tablets)

4 blisters (56 tablets)

10 blisters (140 tablets)

Not all pack sizes may be marketed. VPA22020/018/002 Vm 52127/3035 UK(NI): Vm 52127/5100 UK(GB):

Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH

Heinz-Lohmann Strasse 4

Groden

27472 Cuxhaven

Germany

Tel: +44 3308221732 IE:

PV.IRL@elancoah.com

UK(GB): PV.GBR@elancoah.com

UK(NI):

PV.XXI@elancoah.com

Manufacturer responsible for batch release:

Elanco France S.A.S 26 Rue de la Chapelle

F-68330 Huningue France

Other information

Pharmacodynamics

Benazepril hydrochloride is a prodrug hydrolysed in vivo to its active metabolite, benazeprilat. Benazeprilat is a highly potent and selective inhibitor of the angiotensin converting enzyme (ACE), thus preventing the conversion of inactive angiotensin I to active angiotensin II and thereby also reducing synthesis of aldosterone. Therefore, it blocks effects mediated by angiotensin II and aldosterone, including vasoconstriction of both arteries and veins, retention of sodium and water by the kidney and remodelling effects (including pathological cardiac hypertrophy and degenerative renal changes).

The veterinary medicinal product causes long-lasting inhibition of plasma ACE activity in dogs, with more than 95% inhibition at peak effect and significant activity (>80% in dogs) persisting 24 hours after dosing.

The product reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.

In contrast with other ACE inhibitors, benazeprilat is excreted equally by both biliary and urinary routes in dogs, and therefore no adjustment of the dose of the product is necessary in the treatment of cases with renal insufficiency.

UK(GB) and UK(NI):

Medicines should not be disposed of via wastewater.

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment. Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

