

PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FORTEKOR PLUS 5 mg/10 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

5 mg pimobendan / 10 mg benazepril hydrochloride /tablet

3. PACKAGE SIZE

30 tablets

60 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.

Keep the blister in the outer carton in order to protect from moisture.

Any remaining half tablet should be placed back in the opened blister and stored (for a maximum of 1 day) in the original cardboard carton.

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

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

Vm 52127/5015

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS - Blister**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FORTEKOR PLUS



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

5 mg/10 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

FORTEKOR PLUS 1.25 mg/2.5 mg tablets for dogs
FORTEKOR PLUS 5 mg/10 mg tablets for dogs

2. Composition

Each tablet contains

Active substances:

	pimobendan	benazepril hydrochloride
FORTEKOR PLUS 1.25 mg/2.5 mg tablets	1.25 mg	2.5 mg
FORTEKOR PLUS 5 mg/10 mg tablets	5 mg	10 mg

Excipients:

	iron oxide brown (E172)
FORTEKOR PLUS 1.25 mg/2.5 mg tablets	0.5 mg
FORTEKOR PLUS 5 mg/10 mg tablets	2 mg

The tablets are bilayered, oval, white and light brown, and can be divided into halves along the score line.

3. Target species



Dogs.

4. Indications for use

For the treatment of congestive heart failure due to atrioventricular valve insufficiency or dilated cardiomyopathy in dogs. This veterinary medicinal product is

a fixed dose combination and should only be used in patients whose clinical signs are successfully controlled by administration of the same doses of the individual components (pimobendan and benazepril hydrochloride) given concurrently.

5. Contraindications

Do not use in cases of cardiac output failure due to aortic or pulmonary stenosis. Do not use in cases of hypotension (low blood pressure), hypovolemia (low blood volume), hyponatremia (low blood sodium levels) or acute renal (kidney) failure. Do not use in pregnant or lactating dogs (see section "Special warnings"). Do not use in cases of hypersensitivity to pimobendan, to benazepril hydrochloride or to any ingredient of the tablets.

6. Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:

In cases of chronic kidney disease, it is recommended to check the dog's hydration status before starting therapy, and to monitor plasma creatinine and blood erythrocyte counts during therapy.

As pimobendan is metabolised in the liver, the veterinary medicinal product should not be administered in dogs with severe hepatic insufficiency.

The efficacy and safety of the veterinary medicinal product has not been established in dogs below 2.5 kg body weight or under 4 months of age.

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

Wash hands after use.

People with known hypersensitivity to pimobendan or benazepril hydrochloride should avoid contact with the veterinary medicinal product.

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

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

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy in, or in lactation. Do not use during pregnancy or lactation.

Fertility:

Do not use in breeding animals.

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, benazepril hydrochloride and pimobendan have been given in combination with digoxin and diuretics without demonstrable adverse interactions.

In humans, the combination of ACE inhibitors and non-steroidal anti-inflammatory drugs (NSAIDs) can lead to reduced anti-hypertensive efficacy or impaired kidney function. Therefore the concurrent use of this veterinary medicinal product with NSAIDs or any other medications with a hypotensive effect should be considered carefully before using such combinations.

The combination of this 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. 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 therefore recommend the monitoring of plasma potassium concentrations when using this veterinary medicinal product in combination with a potassium-sparing diuretic because of the risk of hyperkalaemia (high blood potassium).

Overdose:

In case of overdose the dog should be treated symptomatically. Transient reversible hypotension (low blood pressure) may occur in accidental overdose. Therapy should consist of intravenous infusion(s) of warm isotonic saline as required.

Major incompatibilities:

Not applicable.

7. Adverse events

Dogs.

Rare (1 to 10 animals / 10,000 animals treated):
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Increased heart rate ¹ Diarrhoea ² , Vomiting ^{1,2} Anorexia ² , Lethargy ²
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Very rare (<1 animal / 10,000 animals treated, including isolated reports):

Elevated creatinine ³ Incoordination ² Fatigue ²

¹ Moderate. These effects are dose-dependent and can be avoided by reducing the dose in those cases.

² Transient.³At the start of therapy in dogs with chronic kidney disease. 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 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.

This veterinary medicinal product is a fixed combination product which should only be used in dogs which require both active substances to be administered concomitantly at this fixed dose.

The recommended dose range for this veterinary medicinal product is 0.25–0.5 mg pimobendan per kg body weight and 0.5–1 mg benazepril hydrochloride per kg body weight divided into two daily doses. This veterinary medicinal product should be

administered orally, twice daily 12 hours apart (morning and evening) and approximately 1 hour before feeding.

The tablets are breakable along the score line.

The table below may be used for guidance.

Body weight (kg) of dog	Strength and number of tablets to be administered			
	FORTEKOR PLUS 1.25 mg/2.5 mg tablets		FORTEKOR PLUS 5 mg/10 mg tablets	
	Morning	Evening	Morning	Evening
2.5 – 5	0.5	0.5		
5 – 10	1	1		
10 – 20			0.5	0.5
20 – 40			1	1
Over 40 kg			2	2

9. Advice on correct administration

The tablets can be divided into halves if needed.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 25 °C.

Keep the blister in the outer carton in order to protect from moisture.

Any remaining half tablet should be placed back in the opened blister and stored (for a maximum of 1 day) in the original cardboard carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after Exp. The expiry date 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 or your pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Fortekor Plus 1.25 mg/2.5 mg Tablets Vm 52127/5014

Fortekor Plus 5mg/10mg Tablets Vm 52127/5015

Cardboard box containing 30 tablets

Cardboard box containing 60 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 contact details to report suspected adverse reactions:

Elanco GmbH
Heinz-Lohmann Strasse 4
27472 Cuxhaven
Germany
PV.GBR@elancoah.com

Tel: +44 3308221732

Manufacturer responsible for batch release:

Elanco France S.A.S
26 Rue de la Chapelle
F-68330 Huningue
France

17. Other information

POM-V

Gavin Hall
Approved: 09 July 2025