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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder: Elanco GmbH, Heinz-Lohmann-Str. 4
27472 Cuxhaven Germany
Manufacturer responsible for batch release: Elanco France S.A.S
26 Rue de la Chapelle, F-68330 Huningue, France

2. 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
pimobendan/benazepril hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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.

4. INDICATION(S)

For the treatment of congestive heart failure due to atrioventricular valve insufficiency or dilated cardiomyopathy in dogs. FORTEKOR PLUS 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. ADVERSE REACTIONS

Pimobendan:
A moderate positive chronotropic effect and vomiting may occur in rare cases. However, these effects are dose-dependent and can be avoided by reducing the dose in those cases.
Transient diarrhoea, anorexia or lethargy may be observed in rare cases.
Benazepril hydrochloride:
Transient vomiting, incoordination or signs of fatigue have been reported in dogs very rarely, during post authorization experience.
In dogs with chronic kidney disease, benazepril may increase plasma creatinine concentrations at the start of therapy very rarely.
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.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use.
FORTEKOR PLUS 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 FORTEKOR PLUS 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.
FORTEKOR PLUS tablets 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

FORTEKOR PLUS tablets can be divided into halves if needed.

10. WITHDRAWAL PERIOD

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 out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after EXP.

12. SPECIAL WARNING(S)

Special precautions for use in animals
In cases of chronic kidney disease, it is recommended to check the hydration status before starting therapy, and to monitor plasma creatinine and blood erythrocyte counts during therapy.
As pimobendan is metabolised in the liver, the product should not be administered in dogs with severe hepatic insufficiency.
The efficacy and safety of the 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:
Do not use during pregnancy or lactation. The safety of the veterinary medicinal product has not been established in breeding, pregnant or lactating dogs.
Interactions 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 FORTEKOR PLUS with NSAIDs or any other medications with a hypotensive effect should be considered carefully before using such combinations.
The combination of FORTEKOR PLUS 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 FORTEKOR PLUS in combination with a potassium-sparing diuretic because of the risk of hyperkalaemia (high blood potassium).
Overdose (symptoms, emergency procedures, antidotes):
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or your pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

Pack Sizes:

FORTEKOR PLUS 1.25 mg/2.5 mg tablets: Cardboard box containing 30 tablets Cardboard box containing 60 tablets
FORTEKOR PLUS 5 mg/10 mg tablets: Cardboard box containing 30 tablets Cardboard box containing 60 tablets
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.