Annex I

List of the names, pharmaceutical forms, strengths of the veterinary medicinal products, animal species, indications, marketing authorisation holders in the Member States

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strengths	Pharmaceutical forms	Animal species	Indications
Austria	Novartis Animal Health GmbH Biochemiestraße 10 6250 Kundl Austria	Fortekor 5 mg - Filmtabletten für Hunde und Katzen	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs and cats	Treatment of heart failure in dogs Treatment of chronic renal insufficiency in cats
Austria	Novartis Animal Health GmbH Biochemiestraße 10 6250 Kundl Austria	Fortekor 20 mg - Filmtabletten für Hunde	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	Treatment of heart failure in dogs
Austria	Novartis Animal Health GmbH Biochemiestraße 10 6250 Kundl Austria	Fortekor 2,5 mg Gourmet	Benazepril hydrochloride	2.5 mg	Tablets	Dogs and cats	Treatment of heart failure in dogs. Treatment of chronic renal insufficiency in cats
Belgium	Novartis Consumer Health B.V. Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	FORTEKOR 5	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs and cats	Dog: Treatment of heart failure Cat: Retardation of chronic renal insufficiency by reducing the blood pressure.
Belgium	Novartis Consumer Health B.V. Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	FORTEKOR FLAVOUR 5	Benazepril hydrochloride	5 mg	Tablets	Dogs	Treatment of heart failure
Belgium	Novartis Consumer Health B.V. Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	Fortekor 20	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	Treatment of heart failure
Belgium	Novartis Consumer Health B.V. Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	Fortekor Flavour 20	Benazepril hydrochloride	20 mg	Tablets	Dogs	Treatment of heart failure

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strengths	Pharmaceutical forms	Animal species	Indications
Belgium	Novartis Consumer Health B.V. Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	Fortekor 2,5	Benazepril hydrochloride	2.5 mg	Tablets	Dogs and cats	Dog: Treatment of heart failure Cat: Retardation of chronic renal insufficiency by reducing the blood pressure.
Czech Republic	Novartis Animal Health d.o.o. Verovškova 57 1000 Ljubljana Slovenia	FORTEKOR 5 mg potahované tablety	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs and cats	Treatment of heart failure in dogs Treatment of chronic renal insufficiency in cats
Czech Republic	Novartis Animal Health d.o.o. Verovškova 57 1000 Ljubljana Slovenia	FORTEKOR 20 mg potahované tablety	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	Treatment of heart failure in dogs
Denmark	Novartis Healthcare A/S Animal Health Lyngbyvej 172 2100 København Ø Danmark	Fortekor Vet. 5 mg	Benazepril hydrochloride	5 mg	Tablets	Dogs	Heart diseases in dogs
Denmark	Novartis Healthcare A/S Animal Health Lyngbyvej 172 2100 København Ø Danmark	Fortekor Vet. 20 mg	Benazepril hydrochloride	20 mg	Tablets	Dogs	Heart disease in dogs
Denmark	Novartis Healthcare A/S Animal Health Lyngbyvej 172 2100 København Ø Danmark	Fortekor Vet. 2,5 mg	Benazepril hydrochloride	2.5 mg	Tablets	Dogs	Heart disease in dogs
Finland	Novartis Healthcare A/S, Animal Health Lyngbyvej 172 2100 Kööpenhamina Tanska	Fortekor vet. 5 mg	Benazepril hydrochloride	5 mg	Tablets	Dogs	Heart failure in dogs

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strengths	Pharmaceutical forms	Animal species	Indications
Finland	Novartis Healthcare A/S, Animal Health Lyngbyvej 172 2100 Kööpenhamina Tanska	Fortekor vet. 20 mg	Benazepril hydrochloride	20 mg	Tablets	Dogs	Heart failure in dogs
Finland	Novartis Healthcare A/S, Animal Health Lyngbyvej 172 2100 Kööpenhamina Tanska	Fortekor vet. 2,5 mg	Benazepril hydrochloride	2.5 mg	Tablets	Dogs	Cardiac failure in dogs, chronic renal insufficiency in cats
France	Novartis Sante Animale S.A.S. 14 Boulevard Richelieu 92500 Rueil Malmaison France	FORTEKOR F 5	Benazepril hydrochloride	5 mg	Tablets	Dogs and cats	For dogs over 5 kg Treatment of heart failure For cats over 2.5 kg Treatment of chronic renal insufficiency
France	Novartis Sante Animale S.A.S. 14 Boulevard Richelieu 92500 Rueil Malmaison France	FORTEKOR F 20	Benazepril hydrochloride	20 mg	Tablets	Dogs	For dogs over 20 kg Treatment of heart failure
France	Novartis Sante Animale S.A.S. 14 Boulevard Richelieu 92500 Rueil Malmaison France	FORTEKOR 2,5	Benazepril hydrochloride	2.5 mg	Tablets	Dogs and cats	For dogs over 2.5 kg Treatment of heart failure For cats over 2.5 kg Treatment of chronic renal insufficiency
Germany	Novartis Tiergesundheit GmbH Zielstattstr. 40 81379 München Germany	Fortekor Flavour 2,5 mg	Benazepril hydrochloride	2.5 mg	Tablets	Dogs	Treatment of heart failure in dogs, also in addition to the diuretic furosemide and/or the antiarrhythmic drug digoxin
Germany	Novartis Tiergesundheit GmbH Zielstattstr. 40 81379 München Germany	Fortekor 5	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs	Treatment of heart failure in dogs, also in addition to the diuretic furosemide and/or the antiarrhythmic drug digoxin

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strengths	Pharmaceutical forms	Animal species	Indications
Germany	Novartis Tiergesundheit GmbH Zielstattstr. 40 81379 München Germany	Fortekor Flavour 5 mg	Benazepril hydrochloride	5 mg	Tablets	Dogs	Treatment of heart failure in dogs, also in addition to the diuretic furosemide and/or the antiarrhythmic drug digoxin
Germany	Novartis Tiergesundheit GmbH Zielstattstr. 40 81379 München Germany	Fortekor 20	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	Treatment of heart failure in dogs, also in addition to the diuretic furosemide and/or the antiarrhythmic drug digoxin
Germany	Novartis Tiergesundheit GmbH Zielstattstr. 40 81379 München Germany	Fortekor Flavour 20 mg	Benazepril hydrochloride	20 mg	Tablets	Dogs	Treatment of heart failure in dogs, also in addition to the diuretic furosemide and/or the antiarrhythmic drug digoxin
Greece	PREMIER SHUKUROGLOU HELLAS Av.Mesogeion 198 15561 HOLARGOS GREECE	FORTEKOR 5mg	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs	Treatment of heart failure
Greece	PREMIER SHUKUROGLOU HELLAS Av.Mesogeion 198 15561 HOLARGOS GREECE	FORTEKOR 20mg	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	Treatment of heart failure
Greece	PREMIER SHUKUROGLOU HELLAS Av.Mesogeion 198 15561 HOLARGOS GREECE	FORTEKOR Flavour 5	Benazepril hydrochloride	5 mg	Tablets	Dogs	Treatment of heart failure
Greece	PREMIER SHUKUROGLOU HELLAS Av.Mesogeion 198 15561 HOLARGOS GREECE	FORTEKOR Flavour 20	Benazepril hydrochloride	20 mg	Tablets	Dogs	Treatment of heart failure

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strengths	Pharmaceutical forms	Animal species	Indications
Hungary	Novartis Animal Health d.o.o. Verovškova 57 1000 Ljubljana Slovenia	Fortekor 5 mg ízesített tabletta	Benazepril hydrochloride	5 mg	Tablets	Dogs	For the treatment of heart failure in dogs.
Hungary	Novartis Animal Health d.o.o. Verovškova 57 1000 Ljubljana Slovenia	Fortekor 20 mg ízesített tabletta	Benazepril hydrochloride	20 mg	Tablets	Dogs	For the treatment of heart failure in dogs.
Ireland	Novartis Animal Health UK Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	FORTEKOR 5 mg film-coated tablets for dogs and cats.	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs and cats	Treatment of heart failure in dogs. Treatment of chronic renal insufficiency in cats.
Ireland	Novartis Animal Health UK Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	Fortekor 20 mg Film-coated tablets for Dogs	Benazepril hydrochloride	20 mg	Tablets	Dogs	Treatment of heart failure in dogs.
Ireland	Novartis Animal Health UK Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	Fortekor 2.5 mg tablets for Dogs and Cats	Benazepril hydrochloride	2.5 mg	Tablets	Dogs and cats	Treatment of heart failure in dogs. Treatment of chronic renal insufficiency in cats.
Italy	Novartis Animal Health S.p.A. largo Boccioni 1 21040 Origgio (VA) Italy	Fortekor 5	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs and cats	Dogs: Treatment of heart failure at stages 2,3 and 4. For slowing the renal damage progression in chronic kidney disease with proteinuria. Cats: Treatment of chronic renal insufficiency.

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strengths	Pharmaceutical forms	Animal species	Indications
Italy	Novartis Animal Health S.p.A. largo Boccioni 1 21040 Origgio (VA) Italy	Fortekor Flavour 5	Benazepril hydrochloride	5 mg	Tablets	Dogs	Treatment of heart failure at 2nd-3rd and 4th stage. Slow down of the progression of renal damage in chronic kidney disease with proteinuria.
Italy	Novartis Animal Health S.p.A. largo Boccioni 1 21040 Origgio (VA) Italy	Fortekor 20	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	Dogs: Treatment of heart failure at stages 2,3 and 4. For slowing the renal damage progression in chronic kidney disease with proteinuria.
Italy	Novartis Animal Health S.p.A. largo Boccioni 1 21040 Origgio (VA) Italy	Fortekor Flavour 20	Benazepril hydrochloride	20 mg	Tablets	Dogs	Treatment of heart failure at 2nd-3rd and 4th stage. Slow down of the progression of renal damage in chronic kidney disease with proteinuria.
Italy	Novartis Animal Health S.p.A. largo Boccioni 1 21040 Origgio (VA) Italy	Fortekor 2,5	Benazepril hydrochloride	2,5 mg	Tablets	Dogs and cats	Dogs: Treatment of heart failure at stages 2,3 and 4. For slowing the renal damage progression in chronic kidney disease with proteinuria. Cats: Treatment of chronic renal insufficiency.
Luxembourg	Novartis Consumer Health B.V. Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	FORTEKOR 5	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs and cats	Dog: Treatment of heart failure Cat: Retardation of chronic renal insufficiency by reducing the blood pressure.
Luxembourg	Novartis Consumer Health B.V. Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	FORTEKOR Flavour 5	Benazepril hydrochloride	5 mg	Tablets	Dogs	Treatment of heart failure
Luxembourg	Novartis Consumer Health B.V. Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	Fortekor 20	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	Treatment of heart failure

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strengths	Pharmaceutical forms	Animal species	Indications
Luxembourg	Novartis Consumer Health B.V. Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	Fortekor Flavour 20	Benazepril hydrochloride	20 mg	Tablets	Dogs	Treatment of heart failure
Luxembourg	Novartis Consumer Health B.V. Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	Fortekor 2,5	Benazepril hydrochloride	2.5 mg	Tablets	Dogs and cats	Dog: Treatment of heart failure Cat: Retardation of chronic renal insufficiency by reducing the blood pressure.
Norway	Novartis Healthcare A/S Animal Health Lyngbyvej 172 2100 København Ø Danmark	Fortekor vet 5 mg	Benazepril hydrochloride	5 mg	Tablets	Dogs	Treatment of heart failure, especially dilated cardiomyopathy and mitral failure.
Norway	Novartis Healthcare A/S Animal Health Lyngbyvej 172 2100 København Ø Danmark	Fortekor vet 20 mg	Benazepril hydrochloride	20 mg	Tablets	Dogs	Treatment of heart failure, especially dilated cardiomyopathy and mitral failure.
Norway	Novartis Healthcare A/S Animal Health Lyngbyvej 172 2100 København Ø Danmark	Fortekor vet 2,5 mg	Benazepril hydrochloride	2.5 mg	Tablets	Dogs and cats	Dog: Treatment of heart failure, especially dilated cardiomyopathy and mitral failure. Cat: Experimentally to reduce proteinuria in chronic renal failure in which baseline protein/creatinine ratio PCR is >1.
Poland	Novartis Animal Health d.o.o. Verovškova 57 1000 Ljubljana Slovenia	FORTEKOR 5, tabletki powlekane dla psów i kotów	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs and cats	For dogs -Treatment of heart failure For cats -Treatment of chronic renal insufficiency
Poland	Novartis Animal Health d.o.o. Verovškova 57 1000 Ljubljana Slovenia	FORTEKOR 20, tabletki powlekane dla psów	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	For dogs -Treatment of heart failure

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strengths	Pharmaceutical forms	Animal species	Indications
Portugal	Novartis Farma-Produtos Farmacêuticos, S.A. Rua do Centro Empresarial, Edifício 8 Quinta da Beloura 2710-444 Sintra Portugal	FORTEKOR 5 mg comprimidos revestidos para cães e gatos	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs and cats	Dogs: Treatment of heart failure Cats: Treatment of renal insufficiency
Portugal	Novartis Farma-Produtos Farmacêuticos, S.A. Rua do Centro Empresarial, Edifício 8 Quinta da Beloura 2710-444 Sintra Portugal	FORTEKOR Palatável 5 mg comprimidos para cães e gatos	Benazepril hydrochloride	5 mg	Tablets	Dogs and cats	Dogs: Treatment of heart failure. Indicated in chronic renal insufficiency to slow its progression. Cats: Treatment of chronic renal insufficiency.
Portugal	Novartis Farma-Produtos Farmacêuticos, S.A. Rua do Centro Empresarial, Edifício 8 Quinta da Beloura 2710-444 Sintra Portugal	FORTEKOR 20 mg comprimidos revestidos para cães	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	Dogs: Treatment of heart failure
Portugal	Novartis Farma-Produtos Farmacêuticos, S.A. Rua do Centro Empresarial, Edifício 8 Quinta da Beloura 2710-444 Sintra Portugal	FORTEKOR Palatável 20 mg comprimidos para cães	Benazepril hydrochloride	20 mg	Tablets	Dogs	Dogs: Treatment of heart failure. Indicated in chronic renal insufficiency to slow its progression.
Portugal	Novartis Farma-Produtos Farmacêuticos, S.A. Rua do Centro Empresarial, Edifício 8 Quinta da Beloura 2710-444 Sintra Portugal	FORTEKOR Palatável 2,5 mg comprimidos para cães e gatos	Benazepril hydrochloride	2,5 mg	Tablets	Dogs and cats	Dogs: Treatment of heart failure. Indicated in chronic renal insufficiency to slow its progression. Cats: Treatment of chronic renal insufficiency.

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strengths	Pharmaceutical forms	Animal species	Indications
Romania	Novartis Animal Health d.o.o. Verovškova 57 1000 Ljubljana Slovenia	FORTEKOR 5	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs	For treatment of heart failure in dogs.
Romania	Novartis Animal Health d.o.o. Verovškova 57 1000 Ljubljana Slovenia	FORTEKOR 20	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	For treatment of heart failure in dogs.
Slovakia	Novartis Animal Health d.o.o. Verovškova 57 1000 Ljubljana Slovenia	FORTEKOR 5 mg tbl.ad us.vet	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs and cats	Treatment of heart failure in dogs.Treatment of chronic kidney insufficiency in cats.
Slovenia	Novartis Veterina d.o.o. Verovškova 57 1000 Ljubljana Slovenia	FORTEKOR 5 mg filmsko obložene tablete za pse	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs	Treatment of heart failure in dogs.
Slovenia	Novartis Veterina d.o.o. Verovškova 57 1000 Ljubljana Slovenia	FORTEKOR 20 mg filmsko obložene tablete za pse	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	Treatment of heart failure in dogs.
Spain	NOVARTIS SANIDAD ANIMAL, S.L. Calle de la Marina, 206 08013 Barcelona Spain	FORTEKOR 5	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs and cats	Dogs: Treatment of heart failure. Diuretics and/or antiarrhythmics may be used with benazepril when judged appropriate by the veterinarian, but whenever it is thought to be appropriate benazepril alone may be used. Cats: Treatment of chronic renal insufficiency.
Spain	NOVARTIS SANIDAD ANIMAL, S.L. Calle de la Marina, 206 08013 Barcelona Spain	FORTEKOR SABOR 5 mg	Benazepril hydrochloride	5 mg	Tablets	Dogs	Dogs: Treatment of heart failure in dogs. It is indicated in chronic renal insufficiency to slow down its progression.

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strengths	Pharmaceutical forms	Animal species	Indications
Spain	NOVARTIS SANIDAD ANIMAL, S.L. Calle de la Marina, 206 08013 Barcelona Spain	FORTEKOR 20	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	Dogs: Treatment of heart failure. Diuretics and/or antiarrhythmics may be used with benazepril when judged appropriate by the veterinarian, but whenever it is thought to be appropriate benazepril alone may be used.
Spain	NOVARTIS SANIDAD ANIMAL, S.L. Calle de la Marina, 206 08013 Barcelona Spain	FORTEKOR SABOR 20 mg	Benazepril hydrochloride	20 mg	Tablets	Dogs	Dogs: Treatment of heart failure in dogs. It is indicated in chronic renal insufficiency to slow down its progression.
Spain	NOVARTIS SANIDAD ANIMAL, S.L. Calle de la Marina, 206 08013 Barcelona Spain	FORTEKOR SABOR 2,5 mg	Benazepril hydrochloride	2.5 mg	Tablets	Dogs and cats	Dogs: Treatment of heart failure in dogs. It is indicated in chronic renal insufficiency to slow down its progression. Cats: Treatment of chronic renal insufficiency.
Sweden	Novartis Healthcare A/S, Animal Health Lyngbyvej 172 2100 Köpenhamn Danmark	Fortekor vet 5 mg	Benazepril hydrochloride	5 mg	Tablets	Dogs	Treatment of heart failure, especially dilated cardiomyopathy and mitral failure.
Sweden	Novartis Healthcare A/S, Animal Health Lyngbyvej 172 2100 Köpenhamn Danmark	Fortekor vet 20 mg	Benazepril hydrochloride	20 mg	Tablets	Dogs	Treatment of heart failure, especially dilated cardiomyopathy and mitral failure.
Sweden	Novartis Healthcare A/S, Animal Health Lyngbyvej 172 2100 Köpenhamn Danmark	Fortekor vet 2,5 mg	Benazepril hydrochloride	2.5 mg	Tablets	Dogs	Treatment of heart failure, especially dilated cardiomyopathy and mitral failure.

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strengths	Pharmaceutical forms	Animal species	Indications
The Netherlands	Novartis Consumer Health BV Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	Fortekor 5	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs and cats	Dogs: For the symptomatic, adjunctive therapy in the treatment with the diuretic furosemide of heart failure caused by mitral failure or congestive cardiomyopathy. The treatment may improve the effort tolerance and increase survival of dogs with moderate to severe heart failure. Cats: Treatment of chronic renal failure.
The Netherlands	Novartis Consumer Health BV Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	FORTEKOR FLAVOUR 5	Benazepril hydrochloride	5 mg	Tablets	Dogs and cats	Dogs: For the symptomatic, adjunctive therapy in the treatment with the diuretic furosemide of heart failure caused by mitral failure or congestive cardiomyopathy. The treatment may improve the effort tolerance and increase survival of dogs with moderate to severe heart failure. Cats: Treatment of chronic renal failure.
The Netherlands	Novartis Consumer Health BV Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	Fortekor 20	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	Dogs: For the symptomatic, adjunctive therapy in the treatment with the diuretic furosemide of heart failure caused by mitral failure or congestive cardiomyopathy. The treatment may improve the effort tolerance and increase survival of dogs with moderate to severe heart failure.

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strengths	Pharmaceutical forms	Animal species	Indications
The Netherlands	Novartis Consumer Health BV Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	Fortekor Flavour 20	Benazepril hydrochloride	20 mg	Tablets	Dogs	Dogs: For the symptomatic, adjunctive therapy in the treatment with the diuretic furosemide of heart failure caused by mitral failure or congestive cardiomyopathy.
The Netherlands	Novartis Consumer Health BV Claudius Prinsenlaan 142 4818 CP Breda The Netherlands	Fortekor 2,5	Benazepril hydrochloride	2.5 mg	Tablets	Dogs and cats	Dogs: For the symptomatic, adjunctive therapy in the treatment with the diuretic furosemide of heart failure caused by mitral failure or congestive cardiomyopathy. Cats: Treatment of chronic renal failure.
United Kingdom	Novartis Animal Health UK Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	Fortekor 5mg Film-coated Tablets for Dogs and Cats	Benazepril hydrochloride	5 mg	Film-coated tablets	Dogs and cats	Treatment of heart failure in dogs. Treatment of chronic renal insufficiency in cats.
United Kingdom	Novartis Animal Health UK Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	Fortekor 20 mg Film-coated tablets for Dogs	Benazepril hydrochloride	20 mg	Film-coated tablets	Dogs	Treatment of heart failure in dogs.
United Kingdom	Novartis Animal Health UK Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	Fortekor 2.5 mg tablets for Dogs and Cats	Benazepril hydrochloride	2.5 mg	Tablets	Dogs and cats	Treatment of heart failure in dogs. Treatment of chronic renal insufficiency in cats.

Annex II

Scientific conclusions and grounds for amendment of the summaries of product characteristics, labelling and package leaflets

Overall summary of the scientific evaluation of Fortekor and associated names (see annex I)

1. Introduction

Fortekor and associated names is a veterinary medicinal product containing benazepril hydrochloride presented in 2.5 mg, 5 mg and 20 mg flavoured tablets and 5 mg and 20 mg film-coated tablets intended for use in dogs and cats.

Fortekor was initially authorised for use in dogs for the treatment of heart failure, but through national variation applications the treatment of chronic kidney disease (CKD) in cats has been added in several Member States (EU/EEA). In some Member States, however, applications to extend the indication to CKD in cats were not approved, and there are therefore differences in the product information of Fortekor between Member States. During the referral procedure it was noted that divergent national decisions on marketing authorisations have also been taken by Member States regarding the target species dogs where some Member States have authorised the product with an indication for renal failure.

Therefore due to divergent national decisions taken by Member States concerning the authorisations of Fortekor and associated names (5 mg benazepril gydrochloride film-coated tablet), on 16 October 2009, Sweden triggered a referral under Article 34(1) of Directive 2001/82/EC, as amended.

In line with the principles of referrals under Article 34(1) of Directive 2001/82/EC, on 16 September 2010 Sweden sent a revised referral notification under Article 34(1) of Directive 2001/82/EC, and extended the scope of the referral procedure to all Fortekor and associated names tablet strengths and formulations.

The marketing authorisation holders were requested to provide, for the different strengths and formulations, proposals for harmonised product information and supportive data concerning the two target species which formed the basis for the CVMP opinion.

2. Discussion of the data available

Cats

In the preclinical studies presented by the marketing authorisation holders, basic pharmacokinetic and pharmacodynamic properties of benazepril treatment in cats were described. By the use of an experimental model with nephrectomised cats, chronic treatment with benazepril lowered glomerular capillary pressure, raised glomerular ultrafiltration coefficient, sustained single nephron Glomerular Filtration Rate (GFR) in remnant nephrons and reduced systemic hypertension. The differences between groups of cats were, however, minor compared to baseline, and recovery during the study complicated the interpretation of data. No considerable deviations in pharmacokinetics of benazepril were noted after long-term treatment or in cats with renal insufficiency, and no adjustment of dose is therefore necessary.

Safety data from clinical trials have not generated any findings that indicate the need for limitations in the use of Fortekor in cats, and this is reflected by pharmacovigilance data. In the tolerance studies, no significant or dose-related clinical signs of pathological findings were recorded apart from mild hypertrophy/hyperplasia of the juxtaglomerular cells in the kidneys after treatment with 10-20 times the recommended target dose. In the pharmacovigilance data collected since the first authorisation of Fortekor for use in cats, the most frequently reported adverse events include emesis, lethargy, anorexia and diarrhoea. The incidence of adverse events was low (estimated to 0.0066-0.037%), and it cannot be excluded that adverse events are related to severe underlying disease conditions.

Thus, no restrictions in the use of Fortekor in cats have been indicated, but it should be noted, however, that due to possible initial hypotensive effect of angiotensin converting enzyme inhibitor (ACEI) treatment, benazepril should not be administered to animals with hypotension, hypovolemia, hyponatremia or acute renal failure. Pre-existing conditions resulting in decreased renal perfusion should be corrected before ACEI treatment is initiated since ACEI can cause acute renal failure in these cases when angiotensin II-dependent glomerular filtration is blocked. Therefore, appropriate text should be included in relevant sections of the Fortekor product information.

In addition, benazepril has demonstrated teratogenic effects in laboratory animals, and reduction in ovary/oviduct weights was previously observed at treatment of female cats. In the absence of sufficient data in cats (and dogs), it cannot be ruled out that benazepril treatment during pregnancy could be potentially harmful. Furthermore, ACEI treatment is contraindicated during pregnancy and lactation. Therefore, the use of Fortekor during pregnancy and lactation should be contraindicated in cats (and dogs) appropriate text should be added to the relevant sections of the product information.

Data with regard to efficacy of benazepril treatment was obtained from one extensive pivotal clinical field trial including 193 client owned cats with spontaneous CKD. When comparing treated animals with placebo, no effect on survival (primary endpoint) was demonstrated. It could be noted, however, that the median difference in survival between treated cats and placebo with an initial urine protein to creatinine ratio (UPC) ≥ 1.0 was large, but no statistical support for an effect difference was gained. Also, a slight significant overall difference in proteinuria was recorded. When sub-grouping the animals it was shown that the reduction in urine protein was most prominent in the small group of animals with UPC ≥ 1.0. A significant overall difference in UPC was also recorded. The difference in UPC was statistically significant in the group with UPC ≥ 1.0 but not in the group with UPC ≥ 0.2. A beneficial effect of benazepril was noted on appetite for the group with initial UPC ≥ 1.0. No data have been presented that clearly demonstrate benefit of benazepril treatment of cats with CKD on survival. In a pivotal study, no such effect of treatment was seen. Results with regard to secondary endpoints (proteinuria), however, indicated a beneficial effect of benazepril treatment. Proteinuria has in recent years been demonstrated as a prognostic factor for CKD in cats. This in combination with the collected body of data presented in bibliographic references and an increased experience among experts as well as extensive use of benazepril in treatment of CKD in cats indicate that treatment with ACEI is beneficial in cases of CKD in cats with persistent renal proteinuria. The indication for use of Fortekor in CKD could therefore be accepted but should be limited to cats with proteinuria.

Dogs

The marketing authorisation holders have provided proposals for harmonized product information and data in support of treatment of cardiac as well as renal disorders. Since there is little discrepancy in the approved product information between Member States regarding pharmacodynamic properties, pharmacokinetic properties, target animal tolerance and the indication for treatment of heart failure in dogs, only minor changes of the product literature are proposed.

One clinical field trial was submitted to support effect of benazepril treatment of dogs with CKD. In this study, including 49 client owned dogs suffering from CKD, no effect was noted compared to placebo on survival (primary endpoint) or clinical signs neither for the entire group, nor for dogs stratified according to initial UPC > 0.5 (representing dogs with proteinuria). Also, no statistically significant difference in UPC could be demonstrated overall for the treatment period.

An ad-hoc expert group (AHEG) was consulted regarding the scientific evidence base for ACEI in the treatment of chronic kidney disease in dogs. The AHEG agreed that there is no evidence available in public literature to support the use of ACEI in the treatment of dogs with CKD in general and neither the scientific literature nor clinical experience would clearly provide evidence of the efficacy in ACEI in

the treatment of all dogs with CKD. The expert group expressed some potential merits for ACEI treatment in case of proteinuria although no consensus exists regarding which clinical criteria would justify the initiation of treatment. According to the expert group there is some (although limited) scientific evidence for effect of ACEI for treatment of dogs with proteinuria. However, the study supporting this opinion explored the effect from enalapril and an appropriate dose for treatment of CKD with benazepril has not been established[1]. It was emphasized that ACEI treatment should not be employed to any dog with unstable stage 4 kidney disease due to the risk for reduced glomerular filtration rate or worsening azotemia. Furthermore, a precaution regarding combination with non-steroidal anti-inflammatory drugs was regarded appropriate due to the risk connected to lowering the blood pressure in dogs with kidney disease. A precaution in line with this conclusion should be added to the product information to reduce the risk when treating dogs with heart failure and concomitant kidney disease.

3. Benefit-risk assessment

Fortekor and associated names is a veterinary medicinal product containing benazepril hydrochloride presented in 2.5 mg, 5 mg and 20 mg flavoured tablets and 5 mg and 20 mg film-coated tablets intended for use in dogs and cats. The product is authorised for the treatment of heart failure in dogs and in some Member States for treatment of chronic kidney disease in cats and dogs.

Benefit assessment

Direct benefits

Data from clinical trials in conjunction with bibliographic information and experience of clinical experts is regarded to sufficiently support that benazepril treatment is beneficial for cats with CKD and proteinuria. The indication should accommodate the fact that the effect to be expected is likely postponement of disease development whereas cure is not to be expected. The appropriate harmonised indication should be "*Reduction of proteinuria associated with chronic kidney disease".*

Regarding the CKD in dogs, the data derived from the pivotal (and only) clinical trial and the additional bibliographic information does neither provide sufficient information to conclude on an appropriate dose nor adequate support for a beneficial effect during clinical use.

The benefit connected to benazepril treatment of dogs with heart failure is sufficiently support by previously presented data. The appropriate harmonised indication should be "*Treatment of congestive heart failure in dogs*".

Risk assessment

In principle, there are no risks identified that would lead to restrictions in the use of Fortekor in cats with CKD or dogs with heart failure other than those indicated in the product information with amendments.

However, benazepril treatment of dogs with unstable kidney disease involves an increased risk for deterioration of renal function due to the reduction of peripheral blood pressure leading to a decline in glomerular filtration rate and worsening azotemia. Due to this a precaution for treatment of dogs with heart failure and concomitant uncontrolled kidney disease should be added to the product information.

[1] Grauer (2000) Effects of enalapril versus placebo as a treatment for canine idiopathic glomerulonephritis. J Vet Intern Med 2000, 14: 526-533

Evaluation of the benefit-risk balance

Given that no risks has been identified during treatment of cats that would restrict the use and furthermore, that sufficient support for efficacy is available, the benefit-risk balance is regarded positive for Fortekor for the following indication in cats: *"Reduction of proteinuria associated with chronic kidney disease".*

Given that in principle no risks has been identified during treatment of dogs that would restrict the use and furthermore, that sufficient support for efficacy is available the benefit-risk balance is regarded positive for Fortekor for the following indication in dogs: *"Treatment of congestive heart failure in dogs"*. However, a precaution regarding use in dogs with instable kidney disease should be added to the product information since Fortekor treatment of dogs with heart failure and concomitant instable kidney disease could further deteriorate renal function.

In consideration of the fact that sufficient information to support efficacy during treatment of chronic kidney disease in dogs has not been presented, no information on appropriate dose for this condition is available and treatment of CKD is connected to particular risks, the benefit-risk balance for treatment of dogs with chronic kidney disease was regarded as negative. Thus, the chronic kidney disease indication in dogs where approved should be deleted.

Grounds for amendment of the summaries of product characteristics, labelling and package leaflets

Whereas:

- the CVMP considered the primary scope of the referral regarding the efficacy of the product for the treatment of renal disorders in cats and dogs;
- the CVMP reviewed the summaries of products characteristics, labelling and package leaflets proposed by the marketing authorisation holders and considered all the overall submitted data;

the CVMP, concluded that the overall benefit/risk balance for this product remains positive, except for the chronic kidney disease in dogs, subject to the recommended changes in the product information. Therefore the CVMP has recommended the variation of the marketing authorisations for which the summaries of product characteristics, labelling and package leaflets are set out in annex III for Fortekor and associated names as referred in annex I.

Annex III

Summaries of product characteristics, labelling and package leaflets

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Tablets for cats and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Benazepril hydrochloride 2.5 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.
To be completed nationally.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Dogs:
Treatment of congestive heart failure.

Cats:
Reduction of proteinuria associated with chronic kidney disease.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of hypotension, hypovolaemia, hyponatraemia or acute renal failure.
Do not use in cases of cardiac output failure due to aortic or pulmonary stenosis.
Do not use during pregnancy or lactation (section 4.7).

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
No evidence of renal toxicity of the veterinary medicinal product has been observed (in dogs or cats) 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 *"product name" (to be completed nationally)* has not been established in dogs and cats below 2.5 kg body weight.

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

Wash hands after use.
In case of accidental oral ingestion, seek medical advice immediately and show the label or the package leaflet 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.

4.6 Adverse reactions (frequency and seriousness)

In double-blind clinical trials in dogs with congestive heart failure, *"product name" (to be completed nationally)* was well tolerated with an incidence of adverse reactions lower than observed in placebo-treated dogs.

A small number of dogs may exhibit transient vomiting, incoordination or signs of fatigue.

In cats and dogs with chronic kidney disease, "*product name" (to be completed nationally)* 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.

"*Product name"* (*to be completed nationally)* may increase food consumption and body weight in cats.

Emesis, anorexia, dehydration, lethargy and diarrhoea have been reported in rare occasions in cats.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy or lactation. The safety of *"product name" (to be completed nationally)* has not been established in breeding, pregnant or lactating dogs and cats. Benazepril reduced ovary/oviduct weights in cats when administered daily at 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.

4.8 Interaction with other medicinal products and other forms of interaction

In dogs with congestive heart failure, *"product name" (to be completed nationally)* has been given in combination with digoxin, diuretics, pimobendan and anti-arrhythmic veterinary medicinal products 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 renal function. The combination of *"product name" (to be completed nationally)* 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. 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 *"product name" (to be completed nationally)* in combination with a potassium sparing diuretic because of the risk of hyperkalaemia.

4.9 Amounts to be administered and administration route

"Product name" (to be completed nationally) should be given orally once daily, with or without food. The duration of treatment is unlimited.

"Product name" (to be completed nationally) tablets are flavoured and are taken voluntarily by most dogs and cats.

Dogs:
"Product name" (to be completed nationally) should be administered orally 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 (kg)	*"Product name" 2.5 mg (to be completed nationally)*	
	Standard dose	Double dose
2.5 - 5	0.5 tablet	1 tablet
>5 - 10	1 tablet	2 tablets

The dose may be doubled, still administered once daily, to a minimum dose of 0.5 mg/kg (range 0.5-1.0), if judged clinically necessary and advised by the veterinary surgeon.

Cats:
"Product name" (to be completed nationally) should be administered orally at a minimum dose of 0.5 mg (range 0.5-1.0) benazepril hydrochloride/kg body weight once daily according to the following table:

Weight of cat (kg)	*"Product name"2.5 mg (to be completed nationally)*
2.5 – 5	1 tablet
>5 – 10	2 tablets

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

"Product name" (to be completed nationally) reduced erythrocyte counts in normal cats when dosed at 10 mg/kg body weight once daily for 12 months and in normal dogs when dosed at 150 mg/kg body weight once daily for 12 months, but this effect was not observed at the recommended dose during clinical trials in cats or dogs.
Transient reversible hypotension may occur in cases of accidental overdose. Therapy should consist of intravenous infusion of warm isotonic saline.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ACE Inhibitors, plain. ATCvet code: QC09AA07

5.1 Pharmacodynamic properties

Benazepril hydrochloride is a prodrug hydrolysed *in vivo* to its active metabolite, benazeprilat. Benazeprilat is a highly potent and selective inhibitor of 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).

"Product name" (to be completed nationally) causes long-lasting inhibition of plasma ACE activity in dogs and cats, with more than 95% inhibition at peak effect and significant activity (>80% in dogs and >90% in cats) persisting 24 hours after dosing.

"Product name" (to be completed nationally) reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.

In cats with experimental renal insufficiency, *"Product name" (to be completed nationally)* normalized the elevated glomerular capillary pressure and reduced the systemic blood pressure.

Reduction in glomerular hypertension may retard the progression of kidney disease by inhibition of further damage to the kidneys. Placebo controlled clinical field studies in cats with chronic kidney disease (CKD) have demonstrated that *"product name" (to be completed nationally)* significantly reduced levels of urine protein and urine protein to creatinine ratio (UPC); this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane.

No effect of *"product name" (to be completed nationally)* on survival in cats with CKD has been shown, but *"product name" (to be completed nationally)* increased the appetite of the cats, particularly in more advanced cases.

5.2 Pharmacokinetic particulars

After oral administration of benazepril hydrochloride, peak levels of benazepril are attained rapidly (T_{max} 0.5 hour in dogs and within 2 hours in cats) and decline quickly as the active substance is partially metabolised by liver enzymes to benazeprilat. The systemic bioavailability is incomplete (~13% in dogs) due to incomplete absorption (38% in dogs, <30% in cats) and first pass metabolism.

In dogs, peak benazeprilat concentrations (C_{max} of 37.6 ng/ml after a dose of 0.5 mg/kg benazepril hydrochloride) are achieved with a T_{max} of 1.25 hours.
In cats, peak benazeprilat concentrations (C_{max} of 77.0 ng/ml after a dose of 0.5 mg/kg benazepril hydrochloride) are achieved with a T_{max} of 2 hours.
Benazeprilat concentrations decline biphasically: the initial fast phase ($t_{1/2}$=1.7 hours in dogs and $t_{1/2}$=2.4 hours in cats) represents elimination of free drug, while the terminal phase ($t_{1/2}$=19 hours in dogs and $t_{1/2}$=29 hours in cats) reflects the release of benazeprilat that was bound to ACE, mainly in the tissues. Benazepril and benazeprilat are extensively bound to plasma proteins (85-90%), and in tissues are found mainly in the liver and kidney.

There is no significant difference in the pharmacokinetics of benazeprilat when benazepril hydrochloride is administered to fed or fasted dogs. Repeated administration of *"product name" (to be completed nationally)* leads to slight bioaccumulation of benazeprilat (R=1.47 in dogs and R=1.36 in cats with 0.5 mg/kg), steady state being achieved within a few days (4 days in dogs).

Benazeprilat is excreted 54% via the biliary and 46% via the urinary route in dogs and 85% via the biliary and 15% via the urinary route in cats. The clearance of benazeprilat is not affected in dogs or cats with impaired renal function and therefore no adjustment of *"product name" (to be completed nationally)* dose is required in either species in cases of renal insufficiency.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

To be completed nationally.

6.2 Incompatibilities

To be completed nationally.

6.3 Shelf life

To be completed nationally.

6.4 Special precautions for storage

To be completed nationally.

6.5 Nature and composition of immediate packaging

To be completed nationally.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

To be completed nationally.

7. MARKETING AUTHORISATION HOLDER

To be completed nationally.

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed nationally.

10. DATE OF REVISION OF THE TEXT

To be completed nationally.

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be completed nationally.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Tablets for cats and dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Benazepril hydrochloride 2.5 mg

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

To be completed nationally.

5. TARGET SPECIES

Dogs and cats.

6. INDICATIONS

For treatment of congestive heart failure in dogs.
For reduction of proteinuria associated with chronic kidney disease in cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

To be completed nationally.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

To be completed nationally.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. < - To be supplied only on veterinary prescription.>

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Tablets for cats and dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

NOVARTIS

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
To be completed nationally.
Tablets for cats and 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 <and manufacturer>>:
To be completed nationally

<Manufacturer for the batch release:>
To be completed nationally

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Tablets for cats and dogs

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

Each tablet contains 2.5 mg benazepril hydrochloride.

4. INDICATIONS

"Product name" (to be completed nationally) 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 and for reduction of proteinuria associated with chronic kidney disease in cats.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance benazepril hydrochloride or to any ingredient of the tablets.
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 stenosis.
Do not use in pregnant or lactating dogs or cats because the safety of benazepril hydrochloride has not been established during pregnancy or lactation in these species.

6. ADVERSE REACTIONS

Some dogs with congestive heart failure may exhibit vomiting or fatigue during treatment.

In dogs and cats with chronic kidney disease there may be a moderate increase in levels of creatinine, an indicator of kidney function, in the blood. This is likely due to the effect of the medication in reducing the blood pressure within the kidney and is therefore not necessarily a reason for treatment to be stopped, unless the animal is showing other adverse reactions.

"Product name" (to be completed nationally) may increase food consumption and body weight in cats.

Vomiting, poor appetite, dehydration, lethargy and diarrhoea have been reported on rare occasions in cats.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats.

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

"Product name" (to be completed nationally) should be given orally once daily, with or without food. The duration of treatment is unlimited.

"Product name" (to be completed nationally) tablets are flavoured and are taken voluntarily by most dogs and cats.

In dogs *"product name" (to be completed nationally)* should be administered orally 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 (kg)	*"Product name" 2.5 mg (to be completed nationally)*	
	Standard dose	Double dose
2.5 - 5	0.5 tablet	1 tablet
>5 - 10	1 tablet	2 tablets

In dogs with congestive heart failure, 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.

In cats *"product name" (to be completed nationally)* should be administered orally at a minimum dose of 0.5 mg (range 0.5-1.0) benazepril hydrochloride/kg body weight once daily according to the following table:

Weight of cat (kg)	*"Product name"2.5 mg (to be completed nationally)*
2.5 – 5	1 tablet
>5 – 10	2 tablets

9. ADVICE ON CORRECT ADMINISTRATION

To be completed nationally if needed.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Additional precautions to be completed nationally if needed.

12. SPECIAL WARNINGS

Special warnings for dogs and cats
The efficacy and safety of *"product name" (to be completed nationally)* has not been established in dogs and cats below 2.5 kg body weight.

Special precautions for use in animals
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 and blood erythrocyte counts.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.
In case of accidental oral ingestion, seek medical advice immediately and show the label or the package leaflet to the physician.
Pregnant women should take special care to avoid accidental oral exposure because ACE inhibitors have been found to affect the unborn child during pregnancy in humans.

Use during pregnancy, lactation
Do not use during pregnancy or lactation. The safety of *"product name" (to be completed nationally)* has not been established in breeding, pregnant or lactating dogs or cats.

Interactions
Inform the veterinary surgeon if the animal is taking, or has recently taken, any other medicines.
In dogs with congestive heart failure, *"product name" (to be completed nationally)* 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 Anti-Inflammatory Drugs) can lead to reduced anti-hypertensive efficacy or impaired kidney function. The combination of *"product name" (to be completed nationally)* 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 *"product name" (to be completed nationally)* 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.

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

To be completed nationally.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed nationally.

15. OTHER INFORMATION

Pharmacodynamic properties
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).
"Product name" (to be completed nationally) causes long-lasting inhibition of plasma ACE activity in dogs and cats, with more than 95% inhibition at peak effect and significant activity (>80% in dogs and >90% in cats) persisting 24 hours after dosing.

"Product name" (to be completed nationally) reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.

In cats with experimental renal insufficiency, *"product name" (to be completed nationally)* normalized the elevated glomerular capillary pressure and reduced the systemic blood pressure. Reduction in glomerular hypertension may retard the progression of kidney disease by inhibition of further damage to the kidneys. In a clinical trial in cats with chronic kidney disease, *"product name" (to be completed nationally)* significantly reduced protein loss in the urine; this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane. *"Product name" (to be completed nationally)* also increased the appetite of the cats, particularly in more advanced cases.

In contrast with other ACE inhibitors, benazeprilat is excreted equally by both biliary and urinary routes in dogs and 85% via the biliary and 15% via the urinary route in cats, and therefore no adjustment of the dose of *"product name"* (*to be completed nationally)* is necessary in the treatment of cases with renal insufficiency.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Tablets for cats and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Benazepril hydrochloride 5 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.
To be completed nationally

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Dogs:
Treatment of congestive heart failure.

Cats:
Reduction of proteinuria associated with chronic kidney disease.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of hypotension, hypovolaemia, hyponatraemia or acute renal failure.
Do not use in cases of cardiac output failure due to aortic or pulmonary stenosis.
Do not use during pregnancy or lactation (section 4.7).

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

No evidence of renal toxicity of the veterinary medicinal product has been observed (in dogs or cats) 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 *"product name" (to be completed nationally)* has not been established in dogs and cats below 2.5 kg body weight.

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

Wash hands after use.
In case of accidental oral ingestion, seek medical advice immediately and show the label or the package leaflet 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.

4.6 Adverse reactions (frequency and seriousness)

In double-blind clinical trials in dogs with congestive heart failure, *"product name" (to be completed nationally)* was well tolerated with an incidence of adverse reactions lower than observed in placebo-treated dogs.

A small number of dogs may exhibit transient vomiting, incoordination or signs of fatigue.

In cats and dogs with chronic kidney disease, *"product name" (to be completed nationally)* 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.

"*Product name"* (*to be completed nationally)* may increase food consumption and body weight in cats.

Emesis, anorexia, dehydration, lethargy and diarrhoea have been reported in rare occasions in cats.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy or lactation. The safety of *"product name" (to be completed nationally)* has not been established in breeding, pregnant or lactating dogs and cats. Benazepril reduced ovary/oviduct weights in cats when administered daily at 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.

4.8 Interaction with other medicinal products and other forms of interaction

In dogs with congestive heart failure, *"product name" (to be completed nationally)* has been given in combination with digoxin, diuretics, pimobendan and anti-arrhythmic veterinary medicinal products 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 renal function. The combination of *"product name" (to be completed nationally)* 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. 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 *"product name" (to be completed nationally)* in combination with a potassium sparing diuretic because of the risk of hyperkalaemia.

4.9 Amounts to be administered and administration route

"Product name" (to be completed nationally) should be given orally once daily, with or without food. The duration of treatment is unlimited.

"Product name" (to be completed nationally) tablets are flavoured and are taken voluntarily by most dogs and cats.

Dogs:
"Product name" (to be completed nationally) should be administered orally 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 (kg)	*"Product name" 5 mg (to be completed nationally)*	
	Standard dose	Double dose
>5 - 10	0.5 tablet	1 tablet
>10 - 20	1 tablet	2 tablets

The dose may be doubled, still administered once daily, to a minimum dose of 0.5 mg/kg (range 0.5-1.0), if judged clinically necessary and advised by the veterinary surgeon.

Cats:
"Product name" (to be completed nationally) should be administered orally at a minimum dose of 0.5 mg (range 0.5-1.0) benazepril hydrochloride/kg body weight once daily according to the following table:

Weight of cat (kg)	*"Product name" 5 mg (to be completed nationally)*
2.5 – 5	0.5 tablet
>5 – 10	1 tablet

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

"Product name" (*to be completed nationally)* reduced erythrocyte counts in normal cats when dosed at 10 mg/kg body weight once daily for 12 months and in normal dogs when dosed at 150 mg/kg body weight once daily for 12 months, but this effect was not observed at the recommended dose during clinical trials in cats or dogs.
Transient reversible hypotension may occur in cases of accidental overdose. Therapy should consist of intravenous infusion of warm isotonic saline.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ACE Inhibitors, plain. ATCvet code: QC09AA07

5.1 Pharmacodynamic properties

Benazepril hydrochloride is a prodrug hydrolysed *in vivo* to its active metabolite, benazeprilat. Benazeprilat is a highly potent and selective inhibitor of 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).

"Product name" (to be completed nationally) causes long-lasting inhibition of plasma ACE activity in dogs and cats, with more than 95% inhibition at peak effect and significant activity (>80% in dogs and >90% in cats) persisting 24 hours after dosing.

"Product name" (to be completed nationally) reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.

In cats with experimental renal insufficiency, *"Product name" (to be completed nationally)* normalized the elevated glomerular capillary pressure and reduced the systemic blood pressure.

Reduction in glomerular hypertension may retard the progression of kidney disease by inhibition of further damage to the kidneys. Placebo controlled clinical field studies in cats with chronic kidney disease (CKD) have demonstrated that *"Product name" (to be completed nationally)* significantly reduced levels of urine protein and urine protein to creatinine ratio (UPC); this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane.
No effect of *"Product name" (to be completed nationally)* on survival in cats with CKD has been shown, but *"Product name" (to be completed nationally)* increased the appetite of the cats, particularly in more advanced cases.

5.2 Pharmacokinetic particulars

After oral administration of benazepril hydrochloride, peak levels of benazepril are attained rapidly (T_{max} 0.5 hour in dogs and within 2 hours in cats) and decline quickly as the active substance is partially metabolised by liver enzymes to benazeprilat. The systemic bioavailability is incomplete (~13% in dogs) due to incomplete absorption (38% in dogs, <30% in cats) and first pass metabolism.
In dogs, peak benazeprilat concentrations (C_{max} of 37.6 ng/ml after a dose of 0.5 mg/kg benazepril hydrochloride) are achieved with a T_{max} of 1.25 hours.
In cats, peak benazeprilat concentrations (C_{max} of 77.0 ng/ml after a dose of 0.5 mg/kg benazepril hydrochloride) are achieved with a T_{max} of 2 hours.

Benazeprilat concentrations decline biphasically: the initial fast phase ($t_{1/2}$=1.7 hours in dogs and $t_{1/2}$=2.4 hours in cats) represents elimination of free drug, while the terminal phase ($t_{1/2}$=19 hours in dogs and $t_{1/2}$=29 hours in cats) reflects the release of benazeprilat that was bound to ACE, mainly in the tissues. Benazepril and benazeprilat are extensively bound to plasma proteins (85-90%), and in tissues are found mainly in the liver and kidney.

There is no significant difference in the pharmacokinetics of benazeprilat when benazepril hydrochloride is administered to fed or fasted dogs. Repeated administration of *"product name" (to be completed nationally)* leads to slight bioaccumulation of benazeprilat (R=1.47 in dogs and R=1.36 in cats with 0.5 mg/kg), steady state being achieved within a few days (4 days in dogs).

Benazeprilat is excreted 54% via the biliary and 46% via the urinary route in dogs and 85% via the biliary and 15% via the urinary route in cats. The clearance of benazeprilat is not affected in dogs or cats with impaired renal function and therefore no adjustment of *"product name" (to be completed nationally)* dose is required in either species in cases of renal insufficiency.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

To be completed nationally.

6.2 Incompatibilities

To be completed nationally.

6.3 Shelf life

To be completed nationally.

6.4 Special precautions for storage

To be completed nationally.

6.5 Nature and composition of immediate packaging

To be completed nationally.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

To be completed nationally.

7. MARKETING AUTHORISATION HOLDER

To be completed nationally.

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed nationally.

10. DATE OF REVISION OF THE TEXT

To be completed nationally.

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be completed nationally.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Tablets for cats and dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Benazepril hydrochloride 5 mg

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

To be completed nationally.

5. TARGET SPECIES

Dogs and cats.

6. INDICATIONS

For treatment of congestive heart failure in dogs.
For reduction of proteinuria associated with chronic kidney disease in cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

To be completed nationally.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

To be completed nationally.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. < - To be supplied only on veterinary prescription.>

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Tablets for cats and dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

NOVARTIS

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
To be completed nationally.
Tablets for cats and 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 <and manufacturer>>:
To be completed nationally

<Manufacturer for the batch release:>
To be completed nationally

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Tablets for cats and dogs

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

Each tablet contains 5 mg benazepril hydrochloride

4. INDICATIONS

"Product name" (to be completed nationally) 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 and for reduction of proteinuria associated with chronic kidney disease in cats.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance benazepril hydrochloride or to any ingredient of the tablets.
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 stenosis.
Do not use in pregnant or lactating dogs or cats because the safety of benazepril hydrochloride has not been established during pregnancy or lactation in these species.

6. ADVERSE REACTIONS

Some dogs with congestive heart failure may exhibit vomiting or fatigue during treatment.

In dogs and cats with chronic kidney disease there may be a moderate increase in levels of creatinine, an indicator of kidney function, in the blood. This is likely due to the effect of the medication in reducing the blood pressure within the kidney and is therefore not necessarily a reason for treatment to be stopped, unless the animal is showing other adverse reactions.

"*Product name"* (*to be completed nationally)* may increase food consumption and body weight in cats. Vomiting, poor appetite, dehydration, lethargy and diarrhoea have been reported on rare occasions in cats.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats.

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

"Product name" (to be completed nationally) should be given orally once daily, with or without food. The duration of treatment is unlimited.

"Product name" (to be completed nationally) tablets are flavoured and are taken voluntarily by most dogs and cats.

In dogs *"product name" (to be completed nationally)* should be administered orally 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 (kg)	*"Product name" 5 mg (to be completed nationally)*	
	Standard dose	Double dose
5 - 10	0.5 tablet	1 tablet
>10 - 20	1 tablet	2 tablets

In dogs with congestive heart failure, 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.

In cats *"product name" (to be completed nationally)* should be administered orally at a minimum dose of 0.5 mg (range 0.5-1.0) benazepril hydrochloride/kg body weight once daily according to the following table:

Weight of cat (kg)	*"Product name" 5 mg (to be completed nationally)*
2.5 – 5	0.5 tablet
>5 – 10	1 tablet

9. ADVICE ON CORRECT ADMINISTRATION

To be completed nationally if needed.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Additional precautions to be completed nationally if needed.

12. SPECIAL WARNINGS

Special warnings for dogs and cats
The efficacy and safety of *"product name" (to be completed nationally)* has not been established in dogs and cats below 2.5 kg body weight.

Special precautions for use in animals
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 and blood erythrocyte counts.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.
In case of accidental oral ingestion, seek medical advice immediately and show the label or the package leaflet to the physician.
Pregnant women should take special care to avoid accidental oral exposure because ACE inhibitors have been found to affect the unborn child during pregnancy in humans.

Use during pregnancy, lactation
Do not use during pregnancy or lactation. The safety of *"product name" (to be completed nationally)* has not been established in breeding, pregnant or lactating dogs or cats.

Interactions
Inform the veterinary surgeon if the animal is taking, or has recently taken, any other medicines.
In dogs with congestive heart failure, *"product name" (to be completed nationally)* 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 Anti-Inflammatory Drugs) can lead to reduced anti-hypertensive efficacy or impaired kidney function. The combination of *"product name" (to be completed nationally)* 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 *"product name" (to be completed nationally)* 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.

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

To be completed nationally.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed nationally.

15. OTHER INFORMATION

Pharmacodynamic properties
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).
"Product name" (to be completed nationally) causes long-lasting inhibition of plasma ACE activity in dogs and cats, with more than 95% inhibition at peak effect and significant activity (>80% in dogs and >90% in cats) persisting 24 hours after dosing.

"Product name" (to be completed nationally) reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.

In cats with experimental renal insufficiency, *"Product name" (to be completed nationally)* normalized the elevated glomerular capillary pressure and reduced the systemic blood pressure. Reduction in glomerular hypertension may retard the progression of kidney disease by inhibition of further damage to the kidneys. In a clinical trial in cats with chronic kidney disease, *"Product name" (to be completed nationally)* significantly reduced protein loss in the urine; this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane. *"Product name" (to be completed nationally)* also increased the appetite of the cats, particularly in more advanced cases.

In contrast with other ACE inhibitors, benazeprilat is excreted equally by both biliary and urinary routes in dogs and 85% via the biliary and 15% via the urinary route in cats, and therefore no adjustment of the dose of *"product name"* (*to be completed nationally)* is necessary in the treatment of cases with renal insufficiency.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Benazepril hydrochloride 20 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.
To be completed nationally.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Dogs:
Treatment of congestive heart failure.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of hypotension, hypovolaemia, hyponatraemia or acute renal failure.
Do not use in cases of cardiac output failure due to aortic or pulmonary stenosis.
Do not use in pregnancy or lactation (section 4.7).

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

No evidence of renal toxicity of the veterinary medicinal product has been observed in dogs 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.

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

Wash hands after use.
In case of accidental oral ingestion, seek medical advice immediately and show the label or the package leaflet 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.

4.6 Adverse reactions (frequency and seriousness)

In double-blind clinical trials in dogs with congestive heart failure, *"product name" (to be completed nationally)* was well tolerated with an incidence of adverse reactions lower than observed in placebo-treated dogs.

A small number of dogs may exhibit transient vomiting, incoordination or signs of fatigue.

In dogs with chronic kidney disease, *"product name" (to be completed nationally)* 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.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy or lactation. The safety of *"product name" (to be completed nationally)* has not been established in breeding, pregnant or lactating dogs. Embryotoxic effects (foetal urinary tract malformation) were seen in trials with laboratory animals (rats) at maternally non-toxic doses.

4.8 Interaction with other medicinal products and other forms of interaction

In dogs with congestive heart failure, *"product name" (to be completed nationally)* has been given in combination with digoxin, diuretics, pimobendan and anti-arrhythmic veterinary medicinal products 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 renal function. The combination of *"product name" (to be completed nationally)* 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. 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 *"product name" (to be completed nationally)* in combination with a potassium sparing diuretic because of the risk of hyperkalaemia.

4.9 Amounts to be administered and administration route

"Product name" (to be completed nationally) should be given orally once daily, with or without food. The duration of treatment is unlimited.

"Product name" (to be completed nationally) tablets are flavoured and are taken voluntarily by most dogs.

"Product name" (to be completed nationally) should be administered orally 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 (kg)	*"Product name" 20 mg (to be completed nationally)*	
	Standard dose	Double dose
> 20 - 40	0.5 tablet	1 tablet
> 40 - 80	1 tablet	2 tablets

The dose may be doubled, still administered once daily, to a minimum dose of 0.5 mg/kg (range 0.5-1.0), if judged clinically necessary and advised by the veterinary surgeon.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

"Product name" (*to be completed nationally)* reduced erythrocyte counts in normal dogs when dosed at 150 mg/kg body weight once daily for 12 months, but this effect was not observed at the recommended dose during clinical trials in dogs.
Transient reversible hypotension may occur in cases of accidental overdose. Therapy should consist of intravenous infusion of warm isotonic saline.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ACE Inhibitors, plain. ATCvet code: QC09AA07

5.1 Pharmacodynamic properties

Benazepril hydrochloride is a prodrug hydrolysed *in vivo* to its active metabolite, benazeprilat. Benazeprilat is a highly potent and selective inhibitor of 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).

"Product name" (to be completed nationally) causes long-lasting inhibition of plasma ACE activity, with more than 95% inhibition at peak effect and significant activity (>80% in dogs) persisting 24 hours after dosing.

"Product name" (to be completed nationally) reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.

5.2 Pharmacokinetic particulars

After oral administration of benazepril hydrochloride, peak levels of benazepril are attained rapidly (T_{max} 0.5 hour in dogs) and decline quickly as the active substance is partially metabolised by liver enzymes to benazeprilat. The systemic bioavailability is incomplete (~13% in dogs) due to incomplete absorption (38% in dogs) and first pass metabolism.
In dogs, peak benazeprilat concentrations (C_{max} of 37.6 ng/ml after a dose of 0.5 mg/kg benazepril hydrochloride) are achieved with a T_{max} of 1.25 hours.

Benazeprilat concentrations decline biphasically: the initial fast phase ($t_{1/2}$=1.7 hours in dogs) represents elimination of free drug, while the terminal phase ($t_{1/2}$=19 hours in dogs) reflects the release of benazeprilat that was bound to ACE, mainly in the tissues. Benazepril and benazeprilat are extensively bound to plasma proteins (85-90%), and in tissues are found mainly in the liver and kidney.

There is no significant difference in the pharmacokinetics of benazeprilat when benazepril hydrochloride is administered to fed or fasted dogs. Repeated administration of *"product name" (to be completed nationally)* leads to slight bioaccumulation of benazeprilat (R=1.47 in dogs with 0.5 mg/kg), steady state being achieved within a few days (4 days in dogs).

Benazeprilat is excreted 54% via the biliary and 46% via the urinary route in dogs. The clearance of benazeprilat is not affected in dogs with impaired renal function and therefore no adjustment of *"product name" (to be completed nationally)* dose is required in cases of renal insufficiency.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

To be completed nationally.

6.2 Incompatibilities

To be completed nationally.

6.3 Shelf life

To be completed nationally.

6.4 Special precautions for storage

To be completed nationally.

6.5 Nature and composition of immediate packaging

To be completed nationally.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

To be completed nationally.

7. MARKETING AUTHORISATION HOLDER

To be completed nationally.

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed nationally.

10. DATE OF REVISION OF THE TEXT

To be completed nationally.

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be completed nationally.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Tablets for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Benazepril hydrochloride 20 mg

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

To be completed nationally.

5. TARGET SPECIES

Dogs.

6. INDICATIONS

For treatment of congestive heart failure in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

To be completed nationally.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

To be completed nationally.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. < - To be supplied only on veterinary prescription.>

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Tablets for dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

NOVARTIS

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
To be completed nationally.
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 <and manufacturer>>:
To be completed nationally

<Manufacturer for the batch release:>
To be completed nationally

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Tablets for dogs

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

Each tablet contains 20 mg benazepril hydrochloride.

4. INDICATIONS

"Product name" (to be completed nationally) 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.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance benazepril hydrochloride or to any ingredient of the tablets.
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 stenosis.
Do not use in pregnant or lactating dogs because the safety of benazepril hydrochloride has not been established during pregnancy or lactation in these species.

6. ADVERSE REACTIONS

Some dogs with congestive heart failure may exhibit vomiting or fatigue during treatment.

In dogs with chronic kidney disease there may be a moderate increase in levels of creatinine, an indicator of kidney function, in the blood. This is likely due to the effect of the medication in reducing the blood pressure within the kidney and is therefore not necessarily a reason for treatment to be stopped, unless the animal is showing other adverse reactions.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

"Product name" (to be completed nationally) should be given orally once daily, with or without food. The duration of treatment is unlimited.

"Product name" (to be completed nationally) tablets are flavoured and are taken voluntarily by most dogs.

In dogs *"product name" (to be completed nationally)* should be administered orally 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 (kg)	*"Product name" 20 mg (to be completed nationally)*	
	Standard dose	Double dose
>20 - 40	0.5 tablet	1 tablet
> 40 - 80	1 tablet	2 tablets

In dogs with congestive heart failure, 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.

9. ADVICE ON CORRECT ADMINISTRATION

To be completed nationally if needed.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Additional precautions to be completed nationally if needed.

12. SPECIAL WARNINGS

Special warnings for dogs
The efficacy and safety of *"product name" (to be completed nationally)* has not been established in dogs below 2.5 kg body weight.

Special precautions for use in animals
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 and blood erythrocyte counts.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.
In case of accidental oral ingestion, seek medical advice immediately and show the label or the package leaflet to the physician.
Pregnant women should take special care to avoid accidental oral exposure because ACE inhibitors have been found to affect the unborn child during pregnancy in humans.

Use during pregnancy, lactation
Do not use during pregnancy or lactation. The safety of *"product name" (to be completed nationally)* has not been established in breeding, pregnant or lactating dogs.

Interactions
Inform the veterinary surgeon if the animal is taking, or has recently taken, any other medicines.
In dogs with congestive heart failure, *"product name" (to be completed nationally)* 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 Anti-Inflammatory Drugs) can lead to reduced anti-hypertensive efficacy or impaired kidney function. The combination of *"product name" (to be completed nationally)* 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 *"product name" (to be completed nationally)* 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.

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

To be completed nationally.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed nationally.

15. OTHER INFORMATION

Pharmacodynamic properties
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).
"Product name" (to be completed nationally) 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.

"Product name" (to be completed nationally) 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 *"product name"* (*to be completed nationally)* is necessary in the treatment of cases with renal insufficiency.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Film-coated tablets for cats and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Benazepril hydrochloride 5 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.
To be completed nationally

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Dogs:
Treatment of congestive heart failure.

Cats:
Reduction of proteinuria associated with chronic kidney disease.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of hypotension, hypovolaemia, hyponatraemia or acute renal failure.
Do not use in cases of cardiac output failure due to aortic or pulmonary stenosis.
Do not use in pregnancy or lactation (section 4.7).

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

No evidence of renal toxicity of the veterinary medicinal product has been observed (in dogs or cats) 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 *"product name" (to be completed nationally)* has not been established in dogs and cats below 2.5 kg body weight.

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

Wash hands after use.
In case of accidental oral ingestion, seek medical advice immediately and show the label or the package leaflet 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.

4.6 Adverse reactions (frequency and seriousness)

In double-blind clinical trials in dogs with congestive heart failure, *"product name" (to be completed nationally)* was well tolerated with an incidence of adverse reactions lower than observed in placebo-treated dogs.

A small number of dogs may exhibit transient vomiting, incoordination or signs of fatigue.

In cats and dogs with chronic kidney disease, *"product name" (to be completed nationally)* 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.

"*Product name"* (*to be completed nationally)* may increase food consumption and body weight in cats.

Emesis, anorexia, dehydration, lethargy and diarrhoea have been reported in rare occasions in cats.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy or lactation. The safety of *"product name" (to be completed nationally)* has not been established in breeding, pregnant or lactating dogs and cats. Benazepril reduced ovary/oviduct weights in cats when administered daily at 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.

4.8 Interaction with other medicinal products and other forms of interaction

In dogs with congestive heart failure, *"product name" (to be completed nationally)* has been given in combination with digoxin, diuretics, pimobendan and anti-arrhythmic veterinary medicinal products 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 renal function. The combination of *"product name" (to be completed nationally)* 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. 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 *"product name" (to be completed nationally)* in combination with a potassium sparing diuretic because of the risk of hyperkalaemia.

4.9 Amounts to be administered and administration route

"Product name" (to be completed nationally) should be given orally once daily, with or without food. The duration of treatment is unlimited.

Dogs:
"Product name" (to be completed nationally) should be administered orally 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 (kg)	*"Product name" 5 mg (to be completed nationally)*	
	Standard dose	Double dose
>5 – 10	0.5 tablet	1 tablet
>10 – 20	1 tablet	2 tablets

The dose may be doubled, still administered once daily, to a minimum dose of 0.5 mg/kg (range 0.5-1.0), if judged clinically necessary and advised by the veterinary surgeon.

Cats:
"Product name" (to be completed nationally) should be administered orally at a minimum dose of 0.5 mg (range 0.5-1.0) benazepril hydrochloride/kg body weight once daily according to the following table:

Weight of cat (kg)	*"Product name" 5 mg (to be completed nationally)*
2.5 – 5	0.5 tablet
>5 – 10	1 tablet

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

"Product name" (*to be completed nationally)* reduced erythrocyte counts in normal cats when dosed at 10 mg/kg body weight once daily for 12 months and in normal dogs when dosed at 150 mg/kg body weight once daily for 12 months, but this effect was not observed at the recommended dose during clinical trials in cats or dogs.
Transient reversible hypotension may occur in cases of accidental overdose. Therapy should consist of intravenous infusion of warm isotonic saline.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ACE Inhibitors, plain. ATCvet code: QC09AA07

5.1 Pharmacodynamic properties

Benazepril hydrochloride is a prodrug hydrolysed *in vivo* to its active metabolite, benazeprilat. Benazeprilat is a highly potent and selective inhibitor of 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).

"Product name" (to be completed nationally) causes long-lasting inhibition of plasma ACE activity in dogs and cats, with more than 95% inhibition at peak effect and significant activity (>80% in dogs and >90% in cats) persisting 24 hours after dosing.

"Product name" (to be completed nationally) reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.

In cats with experimental renal insufficiency, *"Product name" (to be completed nationally)* normalized the elevated glomerular capillary pressure and reduced the systemic blood pressure.

Reduction in glomerular hypertension may retard the progression of kidney disease by inhibition of further damage to the kidneys. Placebo controlled clinical field studies in cats with chronic kidney disease (CKD) have demonstrated that *"Product name" (to be completed nationally)* significantly reduced levels of urine protein and urine protein to creatinine ratio (UPC); this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane.
No effect of *"Product name" (to be completed nationally)* on survival in cats with CKD has been shown, but *"Product name" (to be completed nationally)* increased the appetite of the cats, particularly in more advanced cases.

5.2 Pharmacokinetic particulars

After oral administration of benazepril hydrochloride, peak levels of benazepril are attained rapidly (T_{max} 0.5 hour in dogs and within 2 hours in cats) and decline quickly as the active substance is partially metabolised by liver enzymes to benazeprilat. The systemic bioavailability is incomplete (~13% in dogs) due to incomplete absorption (38% in dogs, <30% in cats) and first pass metabolism.
In dogs, peak benazeprilat concentrations (C_{max} of 37.6 ng/ml after a dose of 0.5 mg/kg benazepril hydrochloride) are achieved with a T_{max} of 1.25 hours.
In cats, peak benazeprilat concentrations (C_{max} of 77.0 ng/ml after a dose of 0.5 mg/kg benazepril hydrochloride) are achieved with a T_{max} of 2 hours.

Benazeprilat concentrations decline biphasically: the initial fast phase ($t_{1/2}$=1.7 hours in dogs and $t_{1/2}$=2.4 hours in cats) represents elimination of free drug, while the terminal phase ($t_{1/2}$=19 hours in dogs and $t_{1/2}$=29 hours in cats) reflects the release of benazeprilat that was bound to ACE, mainly in the tissues. Benazepril and benazeprilat are extensively bound to plasma proteins (85-90%), and in tissues are found mainly in the liver and kidney.

There is no significant difference in the pharmacokinetics of benazeprilat when benazepril hydrochloride is administered to fed or fasted dogs. Repeated administration of *"product name" (to be completed nationally)* leads to slight bioaccumulation of benazeprilat (R=1.47 in dogs and R=1.36 in cats with 0.5 mg/kg), steady state being achieved within a few days (4 days in dogs).

Benazeprilat is excreted 54% via the biliary and 46% via the urinary route in dogs and 85% via the biliary and 15% via the urinary route in cats. The clearance of benazeprilat is not affected in dogs or cats with impaired renal function and therefore no adjustment of *"product name" (to be completed nationally)* dose is required in either species in cases of renal insufficiency.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

To be completed nationally.

6.2 Incompatibilities

To be completed nationally.

6.3 Shelf life

To be completed nationally.

6.4 Special precautions for storage

To be completed nationally.

6.5 Nature and composition of immediate packaging

To be completed nationally.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

To be completed nationally.

7. MARKETING AUTHORISATION HOLDER

To be completed nationally.

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed nationally.

10. DATE OF REVISION OF THE TEXT

To be completed nationally.

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be completed nationally.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Film-coated tablets for cats and dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Benazepril hydrochloride 5 mg

3. PHARMACEUTICAL FORM

Film-coated tablets.

4. PACKAGE SIZE

To be completed nationally.

5. TARGET SPECIES

Dogs and cats.

6. INDICATIONS

For treatment of congestive heart failure in dogs.

For reduction of proteinuria associated with chronic kidney disease in cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

To be completed nationally.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

To be completed nationally.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. < - To be supplied only on veterinary prescription.>

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Film-coated tablets for cats and dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

NOVARTIS

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
To be completed nationally.
Film-coated tablets for cats and 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 <and manufacturer>>:
To be completed nationally

<Manufacturer for the batch release:>
To be completed nationally

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Film-coated tablets for cats and dogs

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

Each film-coated tablet contains 5 mg benazepril hydrochloride

4. INDICATIONS

"Product name" (to be completed nationally) 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 and for reduction of proteinuria associated with chronic kidney disease in cats.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance benazepril hydrochloride or to any ingredient of the tablets.
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 stenosis.
Do not use in pregnant or lactating dogs or cats because the safety of benazepril hydrochloride has not been established during pregnancy or lactation in these species.

6. ADVERSE REACTIONS

Some dogs with congestive heart failure may exhibit vomiting or fatigue during treatment.

In dogs and cats with chronic kidney disease there may be a moderate increase in levels of creatinine, an indicator of kidney function, in the blood. This is likely due to the effect of the medication in reducing the blood pressure within the kidney and is therefore not necessarily a reason for treatment to be stopped, unless the animal is showing other adverse reactions.

"*Product name"* (*to be completed nationally)* may increase food consumption and body weight in cats. Vomiting, poor appetite, dehydration, lethargy and diarrhoea have been reported on rare occasions in cats.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats.

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

"Product name" (to be completed nationally) should be given orally once daily, with or without food. The duration of treatment is unlimited.

In dogs *"product name" (to be completed nationally)* should be administered orally 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 (kg)	*"Product name" 5 mg (to be completed nationally)*	
	Standard dose	Double dose
5 – 10	0.5 tablet	1 tablet
>10 - 20	1 tablet	2 tablets

In dogs with congestive heart failure, 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.

In cats *"product name" (to be completed nationally)* should be administered orally at a minimum dose of 0.5 mg (range 0.5-1.0) benazepril hydrochloride/kg body weight once daily according to the following table:

Weight of cat (kg)	*"Product name" 5 mg (to be completed nationally)*
2.5 – 5	0.5 tablet
>5 – 10	1 tablet

9. ADVICE ON CORRECT ADMINISTRATION

To be completed nationally if needed.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Additional precautions to be completed nationally if needed.

12. SPECIAL WARNINGS

Special warnings for dogs and cats
The efficacy and safety of *"product name" (to be completed nationally)* has not been established in dogs and cats below 2.5 kg body weight.

Special precautions for use in animals
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 and blood erythrocyte counts.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.
In case of accidental oral ingestion, seek medical advice immediately and show the label or the package leaflet to the physician.
Pregnant women should take special care to avoid accidental oral exposure because ACE inhibitors have been found to affect the unborn child during pregnancy in humans.

Use during pregnancy, lactation
Do not use during pregnancy or lactation. The safety of *"product name" (to be completed nationally)* has not been established in breeding, pregnant or lactating dogs or cats.

Interactions
Inform the veterinary surgeon if the animal is taking, or has recently taken, any other medicines.
In dogs with congestive heart failure, *"product name" (to be completed nationally)* 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 Anti-Inflammatory Drugs) can lead to reduced anti-hypertensive efficacy or impaired kidney function. The combination of *"product name" (to be completed nationally)* 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 *"product name" (to be completed nationally)* 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.

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

To be completed nationally.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed nationally.

15. OTHER INFORMATION

Pharmacodynamic properties
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).
"Product name" (to be completed nationally) causes long-lasting inhibition of plasma ACE activity in dogs and cats, with more than 95% inhibition at peak effect and significant activity (>80% in dogs and >90% in cats) persisting 24 hours after dosing.

"Product name" (to be completed nationally) reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.

In cats with experimental renal insufficiency, *"product name" (to be completed nationally)* normalized the elevated glomerular capillary pressure and reduced the systemic blood pressure. Reduction in glomerular hypertension may retard the progression of kidney disease by inhibition of further damage to the kidneys. In a clinical trial in cats with chronic kidney disease, *"product name" (to be completed nationally)* significantly reduced protein loss in the urine; this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane. *"Product name" (to be completed nationally)* also increased the appetite of the cats, particularly in more advanced cases.

In contrast with other ACE inhibitors, benazeprilat is excreted equally by both biliary and urinary routes in dogs and 85% via the biliary and 15% via the urinary route in cats, and therefore no adjustment of the dose of *"product name"* (*to be completed nationally)* is necessary in the treatment of cases with renal insufficiency.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Film-coated tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Benazepril hydrochloride 20 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.
To be completed nationally

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Dogs:
Treatment of congestive heart failure.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of hypotension, hypovolaemia, hyponatraemia or acute renal failure.
Do not use in cases of cardiac output failure due to aortic or pulmonary stenosis.
Do not use in pregnancy or lactation (section 4.7).

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

No evidence of renal toxicity of the veterinary medicinal product has been observed in dogs 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.

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

Wash hands after use.
In case of accidental oral ingestion, seek medical advice immediately and show the label or the package leaflet 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.

4.6 Adverse reactions (frequency and seriousness)

In double-blind clinical trials in dogs with congestive heart failure, *"product name" (to be completed nationally)* was well tolerated with an incidence of adverse reactions lower than observed in placebo-treated dogs.

A small number of dogs may exhibit transient vomiting, incoordination or signs of fatigue.

In dogs with chronic kidney disease, *"product name" (to be completed nationally)* 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.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy or lactation. The safety of *"product name" (to be completed nationally)* has not been established in breeding, pregnant or lactating dogs. Embryotoxic effects (foetal urinary tract malformation) were seen in trials with laboratory animals (rats) at maternally non-toxic doses.

4.8 Interaction with other medicinal products and other forms of interaction

In dogs with congestive heart failure, *"product name" (to be completed nationally)* has been given in combination with digoxin, diuretics, pimobendan and anti-arrhythmic veterinary medicinal products 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 renal function. The combination of *"product name" (to be completed nationally)* 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. 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 *"product name" (to be completed nationally)* in combination with a potassium sparing diuretic because of the risk of hyperkalaemia.

4.9 Amounts to be administered and administration route

"Product name" (to be completed nationally) should be given orally once daily, with or without food. The duration of treatment is unlimited.

Dogs:
"Product name" (to be completed nationally) should be administered orally 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 (kg)	*"Product name" 20 mg (to be completed nationally)*	
	Standard dose	Double dose
> 20 - 40	0.5 tablet	1 tablet
> 40 - 80	1 tablet	2 tablets

The dose may be doubled, still administered once daily, to a minimum dose of 0.5 mg/kg (range 0.5-1.0), if judged clinically necessary and advised by the veterinary surgeon.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

"Product name" (*to be completed nationally)* reduced erythrocyte counts in normal dogs when dosed at 150 mg/kg once daily for 12 months, but this effect was not observed at the recommended dose during clinical trials in dogs.

Transient reversible hypotension may occur in cases of accidental overdose. Therapy should consist of intravenous infusion of warm isotonic saline.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ACE Inhibitors, plain. ATCvet code: QC09AA07

5.1 Pharmacodynamic properties

Benazepril hydrochloride is a prodrug hydrolysed *in vivo* to its active metabolite, benazeprilat. Benazeprilat is a highly potent and selective inhibitor of 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).

"Product name" (to be completed nationally) causes long-lasting inhibition of plasma ACE activity, with more than 95% inhibition at peak effect and significant activity (>80% in dogs) persisting 24 hours after dosing.

"Product name" (to be completed nationally) reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.

5.2 Pharmacokinetic particulars

After oral administration of benazepril hydrochloride, peak levels of benazepril are attained rapidly (T_{max} 0.5 hour in dogs) and decline quickly as the active substance is partially metabolised by liver enzymes to benazeprilat. The systemic bioavailability is incomplete (~13% in dogs) due to incomplete absorption (38% in dogs) and first pass metabolism.

In dogs, peak benazeprilat concentrations (C_{max} of 37.6 ng/ml after a dose of 0.5 mg/kg benazepril hydrochloride) are achieved with a T_{max} of 1.25 hours.

Benazeprilat concentrations decline biphasically: the initial fast phase ($t_{1/2}$=1.7 hours in dogs) represents elimination of free drug, while the terminal phase ($t_{1/2}$=19 hours in dogs) reflects the release of benazeprilat that was bound to ACE, mainly in the tissues. Benazepril and benazeprilat are extensively bound to plasma proteins (85-90%), and in tissues are found mainly in the liver and kidney.

There is no significant difference in the pharmacokinetics of benazeprilat when benazepril hydrochloride is administered to fed or fasted dogs. Repeated administration of *"product name" (to be completed nationally)* leads to slight bioaccumulation of benazeprilat (R=1.47 in dogs with 0.5 mg/kg), steady state being achieved within a few days (4 days in dogs).

Benazeprilat is excreted 54% via the biliary and 46% via the urinary route in dogs. The clearance of benazeprilat is not affected in dogs with impaired renal function and therefore no adjustment of *"product name" (to be completed nationally)* dose is required in either species in cases of renal insufficiency.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

To be completed nationally.

6.2 Incompatibilities

To *be completed nationally.*

6.3 Shelf life

To be completed nationally.

6.4 Special precautions for storage

To be completed nationally.

6.5 Nature and composition of immediate packaging

To be completed nationally.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

To be completed nationally.

7. MARKETING AUTHORISATION HOLDER

To be completed nationally.

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed nationally.

10. DATE OF REVISION OF THE TEXT

To be completed nationally.

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be completed nationally.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Film-coated tablets for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Benazepril hydrochloride 20 mg.

3. PHARMACEUTICAL FORM

Film-coated tablets.

4. PACKAGE SIZE

To be completed nationally.

5. TARGET SPECIES

Dogs.

6. INDICATIONS

For treatment of congestive heart failure in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

To be completed nationally.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

To be completed nationally.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. < - To be supplied only on veterinary prescription.>

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Film-coated tablets for dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

NOVARTIS

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
To be completed nationally.
Film-coated 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 <and manufacturer>>:
To be completed nationally

<Manufacturer for the batch release:>
To be completed nationally

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Film-coated tablets for dogs

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

Each film-coated tablet contains 20 mg benazepril hydrochloride

4. INDICATIONS

"Product name" (to be completed nationally) 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.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance benazepril hydrochloride or to any ingredient of the tablets.
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 stenosis.
Do not use in pregnant or lactating dogs because the safety of benazepril hydrochloride has not been established during pregnancy or lactation in these species.

6. ADVERSE REACTIONS

Some dogs with congestive heart failure may exhibit vomiting or fatigue during treatment.

In dogs with chronic kidney disease there may be a moderate increase in levels of creatinine, an indicator of kidney function, in the blood. This is likely due to the effect of the medication in reducing the blood pressure within the kidney and is therefore not necessarily a reason for treatment to be stopped, unless the animal is showing other adverse reactions.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

"Product name" (to be completed nationally) should be given orally once daily, with or without food. The duration of treatment is unlimited.

In dogs *"product name" (to be completed nationally)* should be administered orally 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 (kg)	*"Product name" 20 mg (to be completed nationally)*	
	Standard dose	Double dose
>20 – 40	0.5 tablet	1 tablet
> 40 – 80	1 tablet	2 tablets

In dogs with congestive heart failure, 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.

9. ADVICE ON CORRECT ADMINISTRATION

To be completed nationally if needed.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Additional precautions to be completed nationally if needed.

12. SPECIAL WARNINGS

Special warnings for dogs
The efficacy and safety of *"product name" (to be completed nationally)* has not been established in dogs below 2.5 kg body weight.

Special precautions for use in animals
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 and blood erythrocyte counts.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.
In case of accidental oral ingestion, seek medical advice immediately and show the label or the package leaflet to the physician.
Pregnant women should take special care to avoid accidental oral exposure because ACE inhibitors have been found to affect the unborn child during pregnancy in humans.

Use during pregnancy, lactation
Do not use during pregnancy or lactation. The safety of *"product name" (to be completed nationally)* has not been established in breeding, pregnant or lactating dogs.

Interactions
Inform the veterinary surgeon if the animal is taking, or has recently taken, any other medicines.
In dogs with congestive heart failure, *"product name" (to be completed nationally)* 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 Anti-Inflammatory Drugs) can lead to reduced anti-hypertensive efficacy or impaired kidney function. The combination of *"product name" (to be completed nationally)* 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 *"product name" (to be completed nationally)* 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.

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

To be completed nationally.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed nationally.

15. OTHER INFORMATION

Pharmacodynamic properties
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).
"Product name" (to be completed nationally) 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.

"Product name" (to be completed nationally) 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 *"product name"* (*to be completed nationally)* is necessary in the treatment of cases with renal insufficiency.