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EPAR summary for the public

Fortekor Plus

Pimobendan/benazepril hydrochloride

This is a summary of the European public assessment report (EPAR) for Fortekor Plus. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Fortekor Plus.

For practical information about using Fortekor Plus, animal owners/keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Fortekor Plus and what is it used for?

Fortekor Plus is a veterinary medicine used to treat congestive heart failure in dogs. Congestive heart failure is a condition where the heart cannot pump enough blood around the body. This can lead to exercise intolerance (inability to carry out physical activity), difficulty breathing and fluid retention. Fortekor Plus contains two active substances, pimobendan and benazepril hydrochloride. It is only for use in dogs whose heart failure is already being controlled by the same doses of pimobendan and benazepril hydrochloride given as separate medicines.

How is Fortekor Plus used?

Fortekor Plus is available as tablets (pimobendan 1.25 mg/benazepril hydrochloride 2.5 mg and pimobendan 5 mg/benazepril hydrochloride 10 mg) and can only be obtained with a prescription.

Fortekor Plus is given twice daily approximately one hour before feeding. The dose is adjusted according to bodyweight.

For further information, see the package leaflet.

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How does Fortekor Plus work?

Pimobendan is an inotropic (heart stimulant) substance which increases the strength of the contraction of heart muscle and opens up blood vessels carrying blood to and from the heart, which reduces the work of the heart.

Benazepril is a prodrug, a substance that is converted to benazeprilat in the body. Benazeprilat is an 'angiotensin converting enzyme (ACE) inhibitor'. ACE inhibitors lower the production of angiotensin II, a powerful vasoconstrictor (a substance that narrows blood vessels). When the production of angiotensin II is lowered, the blood vessels relax and widen. This allows the blood pressure to drop, reducing the load on the heart.

Both pimobendan and benazepril are already authorised for dogs as separate medicines.

What benefits of Fortekor Plus have been shown in studies?

In a field study involving 67 dogs with congestive heart failure treatment with Fortekor Plus was compared to pimobendan and benazepril given as separate treatments. The main measure of effectiveness was the total score of exercise intolerance, demeanour, breathing effort, coughing and difficulty of breathing at night. The study showed Fortekor Plus to be as effective as pimobendan and benazepril when given as separate treatments.

What are the risks associated with Fortekor Plus?

Fortekor Plus must not be given to dogs with hypertrophic cardiomyopathy (heart muscle disease where the walls of the heart thicken reducing blood output), clinical conditions where heart output cannot increase because of functional or anatomical reasons (e.g. narrowing of the aorta or pulmonary artery). It also must not be given to dogs with low blood pressure, low blood volume, low blood sodium levels or acute (short-term) kidney failure.

The most common side effects with pimobendan (which may affect more than 1 in 10,000 dogs) are an increase in heart rate and vomiting.

The most common side effects with benazepril are short-lived episodes of vomiting, incoordination or signs of tiredness.

For the full list of all restrictions and side effects reported with Fortekor Plus, see the package leaflet.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

Safety information has been included in the summary of product characteristics and the package leaflet for Fortekor Plus, including the appropriate precautions to be followed by healthcare professionals and animal owners/keepers.

People who are hypersensitive (allergic) to pimobendan or benazepril hydrochloride should avoid contact with Fortekor Plus.

If the product is accidentally swallowed by a person, the advice of a doctor should be sought immediately and the package leaflet or label shown to the doctor.

Pregnant women should take special care to avoid accidentally swallowing Fortekor Plus because angiotensin converting enzyme (ACE) inhibitors have been found to affect the unborn child during pregnancy.

Why is Fortekor Plus approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) decided that Fortekor Plus' benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Fortekor Plus

The European Commission granted a marketing authorisation valid throughout the European Union for Fortekor Plus on 8 September 2015.

The full EPAR for Fortekor Plus can be found on the Agency's website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Fortekor Plus, read the package leaflet (also part of the EPAR) or contact your veterinarian or pharmacist.

This summary was last updated in July 2015.