EMA/298336/2012
EMEA/V/C/002524

EPAR summary for the public

Cardalis

Benazepril hydrochloride / spironolactone

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the scientific discussion (also part of the EPAR).

What is Cardalis?

Cardalis is a veterinary medicine that contains two active substances, benazepril hydrochloride and spironolactone. It is available as chewable tablets (2.5 mg/20 mg, 5 mg/40 mg and 10 mg/80 mg).

What is Cardalis used for?

Cardalis is used to treat dogs with congestive heart failure. This is a type of heart disease where the heart cannot pump enough blood around the body. Cardalis is used for congestive heart failure caused by long-term damage to the heart valves.

The tablets are given to the dog once a day with food at a dose of 0.25 mg benazepril hydrochloride and 2 mg spironolactone per kilogram bodyweight. The tablets may either be mixed with a small amount of food offered to the dog just before the main meal, or with the meal itself.

How does Cardalis work?

Spironolactone blocks the actions of aldosterone, a hormone that causes the kidneys to retain salt and water within the body with harmful effects on the cardiovascular system. By blocking aldosterone, spironolactone increases the elimination of salt and water in the urine. This decreases the overall blood volume, reducing the effort needed for the heart to pump blood and thereby improving its function.

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Spironolactone also works on the heart and blood vessels in other ways, although these mechanisms have not yet been fully demonstrated in dogs.

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.

How has Cardalis been studied?

The company presented a laboratory study in Beagle dogs comparing treatment with spironolactone and benazepril as single active substances (in the products Prilactone and Fortekor which are already authorised in the EU) to treatment with Cardalis. The company also presented the results of field studies with the individual active substances given as separate tablets, where the main measure of effectiveness was the number of dogs that died due to heart disease. A field study was conducted in dogs to demonstrate how well Cardalis tablets were taken and how easy they were to give. The main measure of effectiveness was good treatment compliance, which was defined as dogs consuming at least 90% of their tablets. A six month safety study was also conducted in Beagle dogs at up to five times the recommended dose.

What benefit has Cardalis shown during the studies?

In the laboratory study, Cardalis was shown to be bioequivalent to combined treatment with products containing the single active substances (medicines are bioequivalent when they produce the same levels of active substance in the body). This allowed the existing field data on the single active substances to be applied to Cardalis. These studies demonstrated an increased survival in dogs treated concurrently with spironolactone and benazepril compared to benazepril alone. The field study showed Cardalis to be voluntarily and fully consumed 92% of the time when offered with or without food and around 86% of dogs showed good compliance with treatment. The safety study showed Cardalis to have a good safety profile.

What is the risk associated with Cardalis?

Non-castrated male dogs treated with spironolactone may show atrophy (wasting) of the prostrate (a gland of the male reproductive system) that is reversible.

Kidney function and potassium levels in the blood should be monitored before start of treatment in all dogs. Regular monitoring should continue in dogs with reduced kidney function as they may have an increased risk of hyperkalaemia (raised potassium levels in the blood) during treatment. Cardalis should not be given to growing dogs due to its effect on male sex hormones. Cardalis should be used with caution in dogs with liver damage as this may alter the way spironolactone is metabolised (processed) in the liver.

Cardalis must not be used in pregnant or lactating (milk producing) bitches as toxic effects for the foetus were seen in studies of benazepril in rats. It must not be used in dogs intended or used for breeding. Cardalis must not be used in dogs with Addison's disease or hypoadrenocorticism (a condition where the adrenal gland does not produce sufficient amounts of hormones), hyperkalaemia (increased blood potassium levels) or hyponatraemia (reduced blood sodium levels). It must not be used in dogs which are hypersensitive (allergic) to ACE inhibitors or to any of the ingredients. Cardalis must not be used in cases of aortic or pulmonary stenosis (narrowing of the aorta or pulmonary blood vessels) affecting the heart's blood output.

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

People should wash their hands after handling the tablets. People with known hypersensitivity (allergy) to spironolactone or benazepril should avoid contact with Cardalis. Pregnant women should take special care to avoid accidental oral exposure because ACE inhibitors have been found to affect the unborn child. In case of accidental ingestion, medical advice should be sought immediately and the package leaflet or the label shown to the doctor.

Why has Cardalis been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Cardalis exceed the risks and recommended that be given a marketing authorisation. The benefit/risk balance can be found in the scientific discussion module of this EPAR.

Other information about Cardalis:

The European Commission granted a marketing authorisation valid throughout the European Union, for Cardalis on 23 July 2012. Information on the prescription status of this product can be found on the label/outer package.

This summary was last updated in April 2013.