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Spironolactone Ceva (*spironolactone*)¹

An overview of Spironolactone Ceva and why it is authorised in the EU

What is Spironolactone Ceva and what is it used for?

Spironolactone Ceva is a veterinary medicine used to treat dogs with congestive heart failure caused by faulty heart valves. Spironolactone Ceva is used in combination with standard therapy (other heart medicines, including, where necessary, diuretics which increase urine production). It contains the active substance spironolactone.

How is Spironolactone Ceva used?

Spironolactone Ceva is available as tablets and can only be obtained with a prescription. The medicine is given once daily with food and the dose is adjusted according to the dog's bodyweight.

For more information about using Spironolactone Ceva, see the package leaflet or contact your veterinarian or pharmacist.

How does Spironolactone Ceva work?

Spironolactone works by blocking the effects of a hormone called aldosterone in the kidneys, heart and blood vessels. By blocking aldosterone, spironolactone causes the kidneys to excrete sodium and water and retain potassium. This reduces the build-up of water in the tissues and improves heart function. It is accepted there are also other ways in which spironolactone works on the heart and blood vessels in congestive heart failure (although these mechanisms of action have not yet been fully demonstrated in dogs).

What benefits of Spironolactone Ceva have been shown in studies?

Three field studies were conducted with dogs with congestive heart failure due to faulty heart valves. Treatment with Spironolactone Ceva continued for up to 15 months. The studies showed that dogs given the medicine in addition to standard therapy had a longer survival time than the dogs given only standard therapy. A long-term study showed that Spironolactone Ceva treated dogs had less deterioration of their heart disease compared to dogs given only standard therapy.

¹ Previously known as Prilactone.



What are the risks associated with Spironolactone Ceva?

Male dogs may show a reduction in the size of the prostate gland.

Spironolactone Ceva must not be used in dogs with hypoadrenocorticism (a disease resulting from reduced corticosteroid secretion from the adrenal gland), hyperkalaemia (high potassium levels in the blood) or hyponatraemia (low sodium levels in the blood).

Spironolactone Ceva must not be given to dogs with poor kidney function that are receiving non-steroidal anti-inflammatory drugs (NSAIDs).

Spironolactone Ceva must not be given to dogs used for, or intended to be used for, breeding or to bitches during pregnancy or lactation (milk producing), as it has been demonstrated that spironolactone might cause harm to newborn animals.

For the full list of side effects of Spironolactone Ceva, 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 Spironolactone Ceva, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

People who are hypersensitive (allergic) to spironolactone should avoid contact with Spironolactone Ceva. Hands should be washed after handling the medicine.

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.

Why is Spironolactone Ceva authorised in the EU?

The European Medicines Agency decided that Spironolactone Ceva's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Spironolactone Ceva

Prilactone received a marketing authorisation valid throughout the EU on 20 June 2007.

The name of the medicine was changed to Spironolactone Ceva on 25 November 2016.

Further information on Spironolactone Ceva can be found on the Agency's website:

ema.europa.eu/medicines/veterinary/EPAR/spironolactone-ceva.

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