



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EPAR summary for the public

Credelio (*lotilaner*)

An overview of Credelio and why it is authorised in the EU

What is Credelio and what is it used for?

Credelio is a veterinary medicine used to treat flea and tick infestations in dogs and cats. Credelio can be used as part of the management of flea allergy dermatitis (an allergic reaction to flea bites). It contains the active substance lotilaner.

For more information, see the package leaflet.

How is Credelio used?

Credelio is available as chewable tablets in seven different strengths (the lowest two strengths for cats, the rest for dogs) which are given to the animals with food or within 30 minutes after feeding. The dose depends on the animal's weight. After being given to dogs, Credelio kills fleas within 4 hours and ticks within 48 hours of attachment. After being given to cats, Credelio kills fleas within 12 hours and ticks within 24 hours of attachment. Credelio is effective for one month and treatment can be repeated every month. The medicine can only be obtained with a prescription.

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

How does Credelio work?

The active substance in Credelio, lotilaner, acts as an 'ectoparasiticide'. This means that it kills parasites that live on the skin or in the fur of animals, such as fleas and ticks. In order to be exposed to the active substance, fleas and ticks must have attached to the skin and commenced feeding on the animal's blood. Lotilaner kills these parasites that have ingested the blood by acting on their nervous system. It blocks the normal movement of charged particles in and out of nerve cells, especially those associated with gamma-aminobutyric acid (GABA) and glutamate, two substances that convey messages between nerves (neurotransmitters). This results in uncontrolled activity of the nervous system and the paralysis and death of the parasites. Lotilaner kills fleas before they can lay eggs and



so helps to reduce contamination of the animal's environment.

What benefits of Credelio have been shown in studies?

In all studies below animals had natural infestations.

Dogs

In a 12-week field study involving dogs with fleas, 128 dogs were treated with Credelio every four weeks and 64 dogs with a spot-on medicine containing fipronil, another medicine to treat flea infestation. The study showed Credelio to be as effective as the other medicine in reducing the flea counts over the 12 weeks and dogs treated with Credelio had flea counts reduced by 99%.

In a small field study involving dogs with ticks, 47 dogs were treated once with Credelio and 35 dogs were treated with a spot-on medicine containing fipronil and another active substance, (s)-methoprene. The study showed Credelio to be as effective as the other medicine in reducing tick counts over four weeks and tick counts were reduced by 100% for Credelio treated dogs.

A second larger field study of dogs with ticks involved 127 dogs treated with Credelio monthly for 3 months whilst 68 dogs were treated with a spot-on medicine containing fipronil and (s)-methoprene. Credelio was as effective as the other medicine in reducing tick counts and reduced ticks by 99% during the study.

Cats

In a one month study involving cats with fleas, 121 cats were treated with Credelio and 61 cats with a spot-on medicine containing fipronil and (s)-methoprene. Credelio reduced flea counts by 97% over one month and was as effective as the other medicine.

In a further three month study involving cats with ticks, 112 cats were treated with Credelio every month and 57 cats with a spot-on medicine containing fipronil. Credelio was as effective as the other medicine in reducing tick counts and reduced tick counts by 99% during the study.

What are the risks associated with Credelio?

Because ticks must start feeding on the animal in order to be killed by the medicine, the risk of transmission of diseases that they may carry cannot be excluded.

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

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.

Hands should be washed after handling the medicine.

Why is Credelio authorised in the EU?

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

Other information about Credelio

Credelio received a marketing authorisation valid throughout the EU on 25 April 2017.

Further information on Credelio can be found on the Agency's website: ema.europa.eu/Find/medicine/Veterinary_medicines/European_public_assessment_reports.

This overview was last updated in April 2018.