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SCIENCE MEDICINES HEALTH

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Credelio Plus (*lotilaner / milbemycin oxime*)

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

What is Credelio Plus and what is it used for?

Credelio Plus is a veterinary medicine used in dogs to treat concurrent infestations with parasites living outside (ticks and/or fleas) and inside (worms) the animal's body. The medicine can be used as part of the management of flea allergy dermatitis (an allergic reaction to flea bites).

Credelio Plus contains the active substances lotilaner and milbemycin oxime.

How is Credelio Plus used?

Credelio Plus can only be obtained with a prescription.

The medicine is available as chewable tablets in five different strengths. The dose depends on the dog's weight. Tablets should be given with food or after feeding. The necessity, schedule and the frequency of treatment with Credelio Plus should be evaluated by the prescribing veterinarian.

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

How does Credelio Plus work?

The active substances in Credelio Plus work by interfering with the way that signals are passed between nerve cells (neurotransmission) in the nervous system of parasites, resulting in paralysis and death of the parasite.

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. Lotilaner kills parasites that have ingested the animal's blood. In order to be exposed to the active substance, fleas and ticks must therefore have attached to the skin and started feeding on the animal's blood. Lotilaner kills fleas before they can lay eggs and so helps to reduce contamination of the dog's environment. The medicine kills fleas within 4 hours and ticks within 48 hours of attachment and is effective for one month.

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Milbemycin oxime acts as an 'endoparasiticide'. This means that it kills parasites that are present inside the dog's body, such as roundworms, hookworms, whipworms and lungworm. It also prevents heartworm infection.

What benefits of Credelio Plus have been shown in studies?

Fleas

In a 12-week field study conducted in the EU involving dogs naturally exposed to fleas, 138 dogs were treated with Credelio Plus every four weeks and 67 dogs were treated with another medicine containing afoxolaner and milbemycin oxime. The study showed Credelio Plus to be as effective as the comparator medicine in reducing flea counts over the treatment period. In dogs treated with Credelio Plus, flea counts decreased by more than 98%. In both groups, there was a reduction in flea allergy dermatitis.

Ticks

In a 12-week field study conducted in the EU involving dogs naturally exposed to ticks, 149 dogs were treated with Credelio Plus every four weeks and 75 dogs were treated with another medicine containing afoxolaner and milbemycin oxime. The study showed Credelio Plus to be as effective as the comparator medicine in reducing tick counts over the treatment period. In dogs treated with Credelio Plus, tick counts decreased by more than 96%.

Gastrointestinal worms

In a field study conducted in the EU involving dogs naturally exposed to roundworms (*T. canis*, *T. leonina*), hookworm (*A. caninum*) and whipworm (*T. vulpis*), 278 dogs were treated with Credelio Plus and 117 dogs were treated with another medicine containing afoxolaner and milbemycin oxime. The study showed Credelio Plus to be as effective as the comparator medicine based on its reduction of faecal egg counts 7–10 days after treatment (88.9% for *T. canis*, 94.5% for *A. caninum* and 91.5% *T. vulpis*).

Lungworm

The efficacy of Credelio Plus against lungworm (*A. vasorum*) was not demonstrated by means of a field study. Instead, the applicant showed that the way the active substance milbemycin oxime contained in Credelio Plus behaves in the animal's body is similar to how it behaves when included in comparable medicines.

Heartworm

In an 11-month field study conducted in high-prevalence areas in the USA involving dogs naturally exposed to heartworm (*D. immitis*), 112 dogs were treated with Credelio Plus and 126 dogs with another medicine containing lufenuron and milbemycin oxime on a monthly basis. Based on tests for heartworm (antigen and microfilarial tests) before starting treatment and 120, 240 and 330 days afterwards, the study showed that Credelio Plus prevented heartworm infection in 100% of the study animals and that it was as effective as the comparator medicine.

What are the risks associated with Credelio Plus?

The most common side effects with Credelio Plus (which may affect more than 1 but less than 10 animals in 1,000 animals treated) are diarrhoea and vomiting, anorexia (weight loss), muscle tremors, lethargy (lack of energy), itching and changes in behaviour.

Because fleas and ticks must start feeding on the animal in order to be killed by Credelio Plus, there may be a risk of transmission of diseases with which they may be infected.

For the full list of side effects of Credelio Plus, see the package leaflet.

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 and the package leaflet or label shown to the doctor.

Hands should be washed after handling the medicine.

Why is Credelio Plus authorised in the EU?

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

Other information about Credelio Plus

Credelio Plus received a marketing authorisation valid throughout the EU on 14 April 2021.

Further information on Credelio Plus can be found on the Agency's website:

<https://www.ema.europa.eu/medicines/veterinary/EPAR/credelio-plus>.

This overview was last updated in May 2021.