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## EPAR summary for the public

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### Certifect

fipronil/(S)-methoprene/amitraz

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 Certifect?

Certifect is a medicine that contains three active substances, fipronil, (S)-methoprene and amitraz. It is available as a 'spot-on' solution in pipettes already filled with the correct amount needed to treat one dog depending on its weight.

#### What is Certifect used for?

Certifect is used in dogs to treat and prevent infestations with ticks and fleas, and to treat infestations with chewing lice. The medicine can be used in the management of flea allergy dermatitis (an allergic reaction to flea bites).

The content of one full Certifect pipette (appropriate to the dog's weight) is applied directly to the dog's skin, after parting its fur, in two separate spots (halfway down the back of the neck, and at the base of the neck). Treatment should be repeated every month throughout the tick and/or flea seasons.

#### How does Certifect work?

The active substances in Certifect act as 'ectoparasiticides'. This means that they kill parasites that live on the skin or in the fur of animals, such as ticks, fleas and lice. Both fipronil and amitraz kill adult parasites while (S)-methoprene kills parasites at the egg or larval stage. Fipronil works on channels in the cells of the nervous system of ticks and fleas, blocking the transfer of ions in and out of cells,



which results in uncontrolled activity of the central nervous system and death of these parasites. Amitraz stimulates the nervous system of ticks, leading to hyperactivity and death of the ticks. (S)-Methoprene is absorbed into flea eggs or larvae, where it stops their development.

### **How has Certifect been studied?**

The effectiveness of Certifect against ticks and fleas was investigated in both laboratory and field studies. In the main field study, dogs of various breeds, age groups, gender and different weights were treated with either Certifect or a similar 'spot-on' medicine containing fipronil and (S)-methoprene. The effectiveness was measured by counting the numbers of ticks and fleas on the dogs five to eight weeks after treatment. Other studies were performed to investigate if Certifect reduced the risk of transmission of certain tick-borne diseases. Studies were also carried out to look at the effect of shampooing on the effectiveness of the medicine. No studies of Certifect in the treatment of lice were presented, as field studies previously presented for the medicine containing fipronil and (S)-methoprene were considered sufficient.

### **What benefit has Certifect shown during the studies?**

The studies showed that the effect of Certifect is comparable to that of the combination of fipronil with (S)-methoprene in reducing tick and flea counts in dogs. In addition, it has been shown that ticks detach more quickly from treated dogs, which indirectly reduces the risk of transmission of certain tick-borne diseases to dogs from infected ticks.

### **What is the risk associated with Certifect?**

Dogs may show some temporary reactions at the site of application (skin discolouration, hair loss, itching or redness). Dogs may lack energy, show lack of muscle coordination, vomit, have a loss of appetite, diarrhoea, salivate, have blood sugar levels higher than normal, be more sensitive to stimulation, and have a slow heartbeat or slow breathing. These signs generally resolve without treatment and within one day.

For a full list of all side effects reported with Certifect, see the package leaflet.

Certifect must not be used on sick (e.g. with systemic diseases such as diabetes, or with a fever) or recovering animals.

Certifect must not be used on rabbits and cats.

Certifect should not be allowed to enter surface water, as it may be harmful for aquatic organisms.

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

This medicine can cause skin sensitisation and allergic reactions, and people with known allergy to any of the ingredients should avoid contact with the pipette contents. Gloves are recommended. Contact with the application site should be avoided. Children should not be allowed to play with the treated dogs until the application site is dry. The medicine should be applied in a well-ventilated area. People applying the medicine should not smoke, eat or drink, and should wash their hands thoroughly after use. If accidental exposure to the eyes occurs, the eyes should be rinsed with water and in case of accidental exposure to the skin the skin should be washed with soap and water. If side effects are seen, immediate medical assistance should be sought and the package leaflet or label shown to the doctor.

## **Why has Certifect been approved?**

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Certifect outweigh the risks for the approved indications and recommended that Certifect be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

## **Other information about Certifect:**

The European Commission granted a marketing authorisation valid throughout the European Union, for Certifect on 6 May 2011. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in September 2013.