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EPAR summary for the public

Activyl

indoxacarb

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 Activyl?

Activyl is a medicine that contains the active substance indoxacarb. It is available as a clear, colourless to yellow solution presented as a 'spot-on' in pipettes already filled with the correct amount of Activyl needed to treat one cat or dog depending on its weight (5 sizes of pipettes for different dog weights and 2 sizes of pipettes for different cat weights).

What is Activyl used for?

Activyl is used to treat and prevent flea infestations in dogs and cats and to treat flea allergy dermatitis (an allergic reaction to flea bites). Activyl is given as a single treatment.

The contents of one full Activyl pipette (appropriate to the animal and its weight) is applied directly to the skin, after parting the animals fur, onto the back of the cat's neck at the base of its head, or between the shoulder blades and along the back of dogs.

How does Activyl work?

The active substance in Activyl, indoxacarb, is an ectoparasiticide. This means that it will kill parasites that live on the skin or in the fur of animals, such as fleas. After application, indoxacarb is eaten by the insects and activated in their gut into an active compound. This active compound interferes with the parasites' nervous system and causes paralysis and death.

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How has Activyl been studied?

Data were provided on the pharmaceutical quality, the tolerance of the products in cats and dogs, the safety in humans (people in contact with the product) and the safety to the environment.

The effectiveness against the specified parasites was investigated in both laboratory studies and in five field studies (four for the spot-on for cats or dogs only and one for both cats and dogs). In the main field study, dogs and cats of various breeds, age groups, gender and different weights were treated either with Activyl or fipronil, another spot-on medicine which is authorised in the European Union for this indication. The effectiveness was measured by counting of fleas, flea allergy dermatitis assessment, observations on local reactions at the application site after treatment.

What benefit has Activyl shown during the studies?

The results from the laboratory studies and from the field studies, in both cats and dogs, showed that Activyl is as effective as the comparator medicine. A reduction in symptoms of flea allergy dermatitis was recorded in both target species. Efficacy against flea infestations of more than 95% was achieved in dogs by 14 days post treatment and in cats by 42 days post treatment in the study. The studies also showed that Activyl helps with the management of allergic flea dermatitis.

What is the risk associated with Activyl?

Dogs and cats might salivate after treatment. This is thought to be the result of licking the application site straight after treatment. There might also be some temporary itchiness, inflammation or hair loss at the place where the product has been applied to the skin. These signs disappear without further treatment.

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

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

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

Pet owners should avoid skin contact with the pipette contents. They should not smoke, eat or drink, and should wash their hands thoroughly after use. If accidental exposure occurs, the eyes should be rinsed with water or the skin washed with soap and water. The product should be kept away from heat, sparks, open flames or other sources of ignition.

Animals should not be stroked, groomed or allow to groom each other, until the application site is dry, and they should not be allowed to swim or treated with shampoo within 48 hours after treatment. Care should be taken to ensure that the content of the pipette should not come into contact with the eyes of the recipient or other animals.

Why has Activyl been approved?

The CVMP concluded that the benefits of Activyl exceed the risks for the treatment and prevention of flea infestations in dogs and cats. Furthermore, the CVMP concluded that the product is effective as part of a treatment strategy for flea allergy dermatitis and recommended that Activyl be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Activyl:

The European Commission granted a marketing authorisation valid throughout the European Union, for Activyl to Intervet International BV on 18/02/2011. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 18/02/2011.