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EPAR summary for the public

Apoquel

Oclaticinib

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 Apoquel?

Apoquel is a veterinary medicine that contains the active substance oclaticinib. Apoquel tablets are available in three different strengths (3.5 mg, 5.4 mg and 16 mg) to cover a range of dog weights.

What is Apoquel used for?

Apoquel is used in dogs to treat pruritus (itching) associated with allergic dermatitis (inflammation of the skin). It is also used in dogs to treat atopic dermatitis. Treatment should be started at a dose of 0.4 – 0.6 mg per kilogram bodyweight twice a day for up to two weeks. Treatment may then be continued at the same dose given once a day. For the appropriate strength of tablets and number of tablets to be given, see the dosage table in the package leaflet.

How does Apoquel work?

The active substance in Apoquel, oclacitinib, is an immunomodulator (a medicine that changes the activity of the immune system) that works by blocking the action of enzymes known as Janus kinases. These enzymes play an important role in the processes of inflammation and itchiness including those involved in allergic dermatitis and atopic dermatitis in dogs. By blocking the enzymes, Apoquel reduces the inflammation and itchiness associated with the disease.

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How has Apoquel been studied?

The action of Apoquel in pruritus associated with allergic dermatitis was studied in two field studies. In one, Apoquel was compared with prednisolone (an immunosuppressant) in 220 dogs, and in the other Apoquel was compared with placebo (dummy treatment) in 436 dogs. The measure of effectiveness in the studies was based on the assessment by the dog owner of the severity of the pruritus and improvements in the dog's behaviour using a standard scale.

The atopic dermatitis indication was also investigated in two field studies. In both, Apoquel was compared with placebo. One study involved 220 dogs and the second involved 299 dogs. Studies in atopic dermatitis also used assessment of skin lesions on a score known as the canine atopic dermatitis extent and severity index (CADESI).

What benefit has Apoquel shown during the studies?

In the pruritus study comparing Apoquel with prednisolone, both medicines were shown to be effective, with a successful response seen in 68% of dogs treated with Apoquel, and 76% of those treated with prednisolone. When compared with placebo, the success rate was 67% for Apoquel-treated dogs and 29% for placebo-treated dogs.

For atopic dermatitis the treatment success rate for Apoquel-treated dogs in the first study was 66% compared with 4% in placebo-treated dogs using pruritus assessment; the results for CADESI scores were 49% and 4% respectively. The success rates in the second study were similar.

What is the risk associated with Apoquel?

The most common side effects were diarrhoea, vomiting and loss of appetite in decreasing order of frequency.

Apoquel should not be given to dogs less than one year of age or weighing less than 3 kg.

Apoquel should not be given to dogs with signs of immune suppression or progressive cancer as Apoquel has not been studied in such cases.

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

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

Hands should be washed after handling the tablets.

In case of accidental ingestion, medical advice should be sought immediately and the package leaflet or the label shown to the doctor.

Why has Apoquel been approved?

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

Other information about Apoquel:

The European Commission granted a marketing authorisation valid throughout the European Union, for Apoquel on 12/09/2013. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in July 2013.