EMEA/V/C/150

EPAR summary for the public

Palladia

Toceranib

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 Palladia?

Palladia contains toceranib, which belongs to a class of medicines with anticancer activity. It is available as tablets: 10 mg (blue), 15 mg (orange) and 50 mg (red).

What is Palladia used for?

Palladia is used to treat dogs with mast-cell tumours (a type of skin cancer). It is used for tumours that are severe in character (grade 2 or 3), have come back, and cannot be removed with surgery. The usual dose is 3.25 mg per kilogram bodyweight, and the number of tablets to use is carefully calculated for each dog. The tablets are given every other day, with or without food. The duration of treatment depends on the dog's response to treatment.

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How does Palladia work?

The active substance in Palladia, toceranib, is a receptor tyrosine kinase inhibitor. This means that it blocks some specific enzymes known as tyrosine kinases. These enzymes can be found in mast-cell tumours, where they are involved in the growth and spread of cancer cells, and the growth of blood vessels. By blocking these enzymes, Palladia can help to control abnormal cell growth and prevent further development of this type of tumour.

How has Palladia been studied?

A number of studies with Palladia were carried out either in laboratory dogs or in animal patients in veterinary practices or hospitals.

The main study was carried out in two phases in 151 dogs with mast cell tumours. In a first phase (up to six weeks), Palladia was compared with placebo (a dummy treatment). If the disease was getting worse, treatment with Palladia was stopped and the dog was taken out of the study. After six weeks (second phase), the study continued with all the remaining dogs receiving Palladia for an average of another four and a half months.

Treatment started with the recommended dose, but this dose was later reduced or treatment interrupted for a few days in some dogs. The main measures of effectiveness were the ‘objective response’ (an evaluation by the veterinarian of the way the tumour changed during treatment) and the time taken until the tumour started to get worse.

What benefit has Palladia shown during the studies?

Dogs treated with Palladia had greater objective response rates (37%) than dogs treated with placebo (8%) after six weeks of treatment. A complete response (disappearance of the tumour) was seen in around 8% and a partial response (shrinkage of the tumour) was seen in around 29% of the dogs treated with Palladia. For Palladia-treated dogs, it also took longer for the tumour to get worse (nine to ten weeks on average) than in those receiving placebo (three weeks on average).

What is the risk associated with Palladia?

The most common side effects with Palladia are diarrhoea and vomiting, loss of appetite, lethargy (lack of energy), neutropenia (low white blood cell counts), difficulty moving (lameness) and weight loss. These reactions are usually mild to moderate and temporary. Dogs should be regularly monitored for side effects by the veterinarian (at the beginning of treatment, this should be at least once per week). In case of side effects, the veterinarian might decide to lower the dose of Palladia or to stop treatment, either temporarily or permanently.

Palladia must not be used in dogs less than two years of age or weighting less than 3 kg, in bitches that are pregnant or lactating, or in dogs intended for breeding. It should not be used in dogs that may be hypersensitive (allergic) to toceranib or any of the other ingredients. It must not be used in dogs with bleeding in the stomach or gut. For a full list of all side effects or precautions, see the Package Leaflet.

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

The tablets must be given whole and should not be divided, broken or ground up. If broken tablets, or the vomit, urine or faeces of a treated dog comes into contact with the skin or eyes, rinse immediately with plenty of water. Children should not have close contact with the medicine, or with the faeces or vomit of treated dogs. If Palladia is taken accidentally, seek medical advice immediately and show the Package Leaflet or the label to the doctor. For more information, see the Package Leaflet.

Why has Palladia been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Palladia exceed the risks for the treatment of non-resectable Patnaik grade II (intermediate grade) or III (high grade), recurrent, cutaneous mast cell tumours in dogs and recommended that Palladia be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Palladia:

The European Commission granted a marketing authorisation valid throughout the European Union, for Palladia on 23.09.2009. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in 06.2013.