European Medicines Agency
Veterinary Medicines

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

MASIVET

EPAR summary for the public

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 Masivet?

Masivet contains masitinib, which belongs to a class of medicines having an anticancer action. It is available as round, orange tablets (50 and 150 mg).

What is Masivet used for?

Masivet is used to treat dogs with mast-cell tumours (a type of cancer). It is used for tumours which are severe in character (grade 2 or 3) and which cannot be removed with surgery. It is only used if the presence of a mutated form of the receptor protein c-kit in the tumours has been confirmed before the start of treatment.

The tablets are given by mouth, once a day. The dose depends on the weight of the dog being treated.. The duration of treatment depends on the dog's response to treatment.

How does Masivet work?

The active substance in Masivet, masitinib, is a protein-tyrosine kinase inhibitor. This means that it blocks some specific enzymes known as tyrosine kinases. These enzymes can be found in some receptors on the surface of cells, including the c-kit receptor. Some types of mast-cell tumour are linked to a mutation that causes excessive action of c-kit and stimulates the mast cells to divide uncontrollably. By blocking these receptors, Masivet might help to control cell division, preventing further development of the tumours with this particular mutation.

How has Masivet been studied?

A number of studies with Masivet were carried out either in laboratory dogs or in animal patients at veterinary practises in Europe and in the USA. The main study compared the effectiveness of Masivet at the recommended dose of 12.5 mg per kilogramme bodyweight once a day with placebo (a dummy treatment). The study included dogs of various breeds and both sexes with mast-cell tumours that had come back after surgery or could not be removed with surgery. The study population included dogs whose tumours contained mutated or normal ('wild-type') c-kit receptors.

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What benefit has Masivet shown during the studies?

In the dogs whose tumours contained mutated c-kit receptors, it took longer for the tumour to get worse when dogs received Masivet (median of 241 days) than in those receiving placebo (median of 83 days).

What is the risk associated with Masivet?

The most common side effects with Masivet are gastrointestinal reactions (diarrhoea and vomiting) and hair loss. These reactions are usually mild to moderate and temporary, last for up to four weeks. Dogs under Masivet treatment should be regularly monitored for side effects by the veterinarian (at least monthly). In case of side effects, the veterinarian might decide to lower the dose of Masivet or to discontinue treatment.

Masivet must not be used in dogs with certain kinds of liver or kidney problems, or anaemia (low red blood cell counts) or neutropenia (low white blood cell counts). It must not be used in dogs less than six months of age or less than 4 kg in weight, or bitches that are pregnant or lactating. It should not be used in dogs that may be hypersensitive (allergic) to masitinib or any of the other ingredients.
For a full list of all side-effects reported with Masivet, see the Package Leaflet.

Four to six weeks after starting the treatment with Masivet, the veterinarian should check if the treatment is likely to be successful.

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

The tablets must be administered 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 treated dogs, or their faeces or vomit. If Masivet is taken accidentally, seek medical advice immediately and show the Package Leaflet or the label to the doctor. Do not eat, drink or smoke while treating a dog.
For more information, see the Package Leaflet.

Why has Masivet been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Masivet exceed the risks for the treatment of non-resectable mast cell tumours (grade 2 or 3) that have a confirmed mutated c-kit tyrosine kinase receptor and recommended that Masivet be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Masivet:

The European Commission granted a marketing authorisation valid throughout the European Union, for Masivet to AB Science S.A. on 17 November 2008. Information on the prescription status of this product may be found on the label/outer package.
Because this disease is a life threatening condition and the overall number of dogs affected is expected to be low, the CVMP guidelines on "Minor-Use-Minor-Species (MUMS) data requirements" were applied when assessing the dossier.

This summary was last updated on May 2009.