



## EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

### IBAFLIN

#### 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 Ibaflin?

Ibaflin contains ibafloxacin, which belongs to a class of medicines having an antibiotic action. Ibaflin is available as tablets (30, 150, 300 and 900 mg) and as oral gels (3 and 7.5%).

#### What is Ibaflin used for?

Ibaflin is used to treat the infections in dogs and cats:

- skin infections, including shallow and deep 'pyoderma', infected wounds and abscesses caused by bacteria such as *Staphylococci*, *E. coli*, *Proteus* species and *Pasteurella* species,
- upper respiratory tract infections caused by *Staphylococci*, *E. coli* and *Klebsiella* species.

It is also used in dogs to treat acute (short-lived), uncomplicated infections of the urinary tract caused by *Staphylococci*, *Proteus* species, *Enterobacter* species, *E. coli* and *Klebsiella* species.

Ibaflin is given by mouth. Dogs are treated using the tablets, except for skin infection, where in addition to the tablets either strengths of the oral gel may be used. Cats are treated using the 3% oral gel. The dose and duration of treatment depend on the nature and severity of the infection, the weight and species of the animal being treated, and the animal's response to treatment. The standard dose is 15 mg per kilogram body weight once a day for the length of time determined by your veterinarian. For more information, see the Package Leaflet.

#### How does Ibaflin work?

Ibafloxacin, is an antibiotic belonging to the class 'fluoroquinolones'. It works by blocking an enzyme called 'DNA gyrase', which is important in allowing bacteria to make copies of their DNA. This enzyme is only found in bacterial cells, and does not have a similar function in animal cells. By blocking DNA gyrase, ibafloxacin prevents the bacteria from making DNA and stops them making proteins and growing, resulting in their death. A strain which is resistant to one type of fluoroquinolone will also be resistant to other members of the class of fluoroquinolones. The use of ibafloxacin may result in an increase in the prevalence of resistant strains in the target species although this risk is likely to be less of a concern due to the treatment of individual animals with this product.

### **How has Ibaflin been studied?**

Ibaflin tablets have been studied in dogs, looking at their effectiveness in treating skin, urinary tract and respiratory tract infections. The oral gel has been studied in cats looking at skin, respiratory tract and urinary tract infections. In these studies, the effects of Ibaflin were compared with those of other antibiotics (marbofloxacin, enrofloxacin or amoxicillin/clavulanic acid).

From data of two different clinical trials, comparable efficacy was shown between the Ibaflin gel formulations and a positive control to support the claims for skin (soft tissue infections – wounds, abscesses) and upper respiratory tract infections in cats for the oral gel formulation. The indication for treatment of urinary infections in cats was not accepted. Ibaflin oral gel is indicated in dogs for the treatment of skin infections (pyoderma – superficial and deep, wounds, abscesses). Comparable efficacy of the gel formulation to the tablet formulation was shown for dogs in a clinical trial.

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

Ibaflin tablets were at least as effective as the comparator antibiotics in treating skin, urinary tract and upper tract respiratory infections in dogs. The tablets and oral gel were of comparable effectiveness in treating skin infections in dogs.

The oral gel was also at least as effective as the comparator antibiotic (amoxicillin/clavulanic acid) in treating skin and upper respiratory tract infections in cats. However, the results were insufficient to support the use of Ibaflin in the treatment of urinary tract infections in cats.

### **What are the side-effects associated with Ibaflin?**

Diarrhoea, soft faeces, vomiting, dullness (lack of responsiveness) and anorexia (loss of appetite) occur with low frequency in dogs and cats given Ibaflin. Salivation can also occur with the oral gel. These effects are mild and temporary.

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

People who are hypersensitive (allergic) to quinolones should avoid any contact with Ibaflin. Medical advice should be sought if the tablets are swallowed accidentally, particularly by a child.

### **Why has Ibaflin been approved?**

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Ibaflin exceed the risks for the treatment of skin infections, and respiratory tract infections (upper tract) in dogs and cats, and acute, uncomplicated urinary tract infections in dogs, and recommended that Ibaflin be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

### **Other information about Ibaflin:**

The European Commission granted a marketing authorisation valid throughout the European Union for Ibaflin to Intervet International B.V. on 13 June 2000. The marketing authorisation was renewed on 13 June 2005. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in September 2007.