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EPAR summary for the public

Veraflox

Pradofloxacin

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 Veraflox?

Veraflox is a medicine that contains pradofloxacin. It is available as brownish tablets containing 15 mg, 60 mg or 120 mg pradofloxacin, and as a yellowish/beige coloured oral suspension, containing 25 mg/ml pradofloxacin.

What is Veraflox used for?

Veraflox 15 mg tablets can be used in both cats and dogs. The 60 mg and 120 mg tablets are only for use for dogs, and Veraflox oral suspension is only for use in cats.

In dogs, Veraflox is used to treat some skin infections, including wound infections, and acute urinary tract infections caused by certain specific bacteria. It can also be used in conjunction with dental treatment in dogs with severe gum infections.

In cats, Veraflox is used to treat acute infections of the upper respiratory tract caused by certain specific bacteria. In addition, the oral suspension can also be used to treat some skin infections, including wound infections and abscesses, caused by certain specific bacteria.

The dose and duration of treatment depend on the species of the animal being treated and its body weight, the nature and severity of the infection, and the animal's response to the treatment. The standard dose for tablets is 3 mg pradofloxacin per kilogram body weight once a day. For the oral



suspension it is 5 mg pradofloxacin per kilogram body weight once a day. For more information see the package leaflet.

How does Veraflox work?

The active substance in Veraflox, pradofloxacin, belongs to a group of antibiotics called 'fluoroquinolones'. Pradofloxacin works by blocking some of the enzymes that are important in allowing bacteria to make copies of their DNA. By blocking two enzymes called 'DNA gyrase' and 'topoisomerase IV', pradofloxacin stops the bacteria from growing and multiplying. The full list of bacteria against which Veraflox is active can be found in the Summary of Product Characteristics (SPC).

How has Veraflox been studied?

The company presented the results of studies looking at the effectiveness of Veraflox against a range of bacterial infections in cats and dogs. In dogs, the medicine was studied in some skin, urinary tract and gum infections caused by certain specific bacteria. In cats, the medicine was studied in acute infections of the upper respiratory tract and also some skin infections caused by certain specific bacteria. In all of the studies the effectiveness of Veraflox was compared with antibiotics that are commonly used for the treatment of the infections studied (amoxicillin with or without clavulanic acid for the skin and urinary tract infections, and clindamycin for the gum infections).

What benefit has Veraflox shown during the studies?

The studies showed that Veraflox was at least as effective as the comparator medicines in all indications. Veraflox is well tolerated in cats and dogs with mild transient gastro-intestinal disturbances, including vomiting, being observed only in rare cases.

What is the risk associated with Veraflox?

The most common side effects in dogs and cats are mild transient gastro-intestinal disturbances including vomiting, although these have only been observed rarely.

Veraflox must not be used in animals that may be hypersensitive (allergic) to fluoroquinolone antibiotics.

Veraflox must not be used in young growing dogs, in kittens below 6 weeks of age, in animals with joint problems caused by damage to the cartilage, or in animals with central nervous system disorders such as epilepsy. Veraflox must not be used in female animals that are pregnant or lactating.

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

Veraflox products can be harmful to children if they are accidentally swallowed. Therefore all products should be kept out of the reach and sight of children.

People who are hypersensitive (allergic) to quinolone antibiotics should avoid any contact with Veraflox.

People should ensure that Veraflox does not come into contact with their skin or eyes. In case of contact, rinse immediately with plenty of water. Do not eat, drink or smoke while handling Veraflox products. Wash hands after using these products.

If Veraflox is swallowed 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 Veraflox been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Veraflox exceed the risks for the treatment of certain specified infections in dogs and cats and recommended that Veraflox be given a marketing authorisation. More information on the benefit-risk balance can be found in the Scientific Discussion part of this EPAR.

Other information about Veraflox:

The European Commission granted a marketing authorisation valid throughout the European Union, for Veraflox to Bayer Animal Health GmbH on 12/04/2011. Information on the prescription status of this product can be found on the label/outer package.

This summary was last updated on 12/04/2011.