

PACKAGE LEAFLET: Veraflox 15 mg tablets for dogs and cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder : Bayer Animal Health GmbH, D-51368 Leverkusen Germany
Manufacturer responsible for batch release: KVP Pharma +Veterinär Produkte GmbH Projensdorfer Str. 324, D-24106 Kiel, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 15 mg tablets for dogs and cats pradofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each tablet contains:

Active substance: Pradofloxacin 15 mg

Brownish single-scored tablets with "P15" on one side. The tablet can be divided into equal doses.

4. INDICATIONS

Dogs:

Treatment of:

- wound infections caused by susceptible strains of the *Staphylococcus intermedius* group (including *S. pseudintermedius*),
- superficial and deep pyoderma caused by susceptible strains of the *Staphylococcus intermedius* group (including *S. pseudintermedius*),
- acute urinary tract infections caused by susceptible strains of *Escherichia coli* and the *Staphylococcus intermedius* group (including *S. pseudintermedius*) and
- as adjunctive treatment to mechanical or surgical periodontal therapy in the treatment of severe infections of the gingiva and periodontal tissues caused by susceptible strains of anaerobic organisms, for example *Porphyromonas* spp. and *Prevotella* spp. (see section "Special Warnings").

Cats:

Treatment of:

- acute infections of the upper respiratory tract caused by susceptible strains of *Pasteurella multocida*, *Escherichia coli* and the *Staphylococcus intermedius* group (including *S. pseudintermedius*).

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Dogs:

Do not use in dogs during the period of growth as developing articular cartilage may be affected. The period of growth depends on the breed. For the majority of breeds, pradofloxacin-containing veterinary medicinal products must not be used in dogs of less than 12 months of age and in giant breeds less than 18 months.

Do not use in dogs with persisting articular cartilage lesions, since lesions may worsen during treatment with fluoroquinolones.

Do not use in dogs with central nervous system (CNS) disorders, such as epilepsy, as fluoroquinolones could possibly cause seizures in predisposed animals.

Do not use in dogs during pregnancy and lactation (see section "Special Warnings").

Cats:

Due to the lack of data, pradofloxacin should not be used in kittens aged less than 6 weeks.

Pradofloxacin has no effects on the developing cartilage of kittens of 6 weeks of age and older. However the product should not be used in cats with persisting articular cartilage lesions, as these lesions may worsen during treatment with fluoroquinolones.

Do not use in cats with central nervous system (CNS) disorders, such as epilepsy, as fluoroquinolones could potentially cause seizures in predisposed animals.

Do not use in cats during pregnancy and lactation (see section "Special Warnings").

6. ADVERSE REACTIONS

Mild transient gastro-intestinal disturbances including vomiting have been observed in rare cases in dogs and cats.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated-)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs, cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use.

Doses

The recommended dose is 3 mg/kg bodyweight of pradofloxacin once daily according to the following tables. To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. When the dose requires a half tablet to be used the remaining portion should be given at the next administration.

Dogs:

Bodyweight of Dog (kg)	Number of 15 mg tablets	Pradofloxacin dose (mg/kg bw)
>3.4 – 5	1	3 – 4.4
5 – 7.5	1½	3 – 4.5
7.5 – 10	2	3 – 4.
10 – 15	3	3 – 4.5

For dogs over 15 kg, use 60 mg or 120 mg pradofloxacin tablets.

Cats:

Bodyweight of Cat (kg)	Number of 15 mg tablets	Pradofloxacin dose (mg/kg bw)
>3.4 – 5	1	3 – 4.4
5 – 7.5	1½	3 – 4.5
7.5 – 10	2	3 – 4

Duration of treatment

The medication should be administered for as long as advised by your veterinarian. The duration of treatment depends on the severity of the infection and how well the medicine works in your pet. For most infections the following durations of treatment are recommended:

Dogs:

Indication	Duration of treatment(days)
Infections of the skin:	
Superficial pyoderma	14 – 21
Deep pyoderma	14 – 35
Wound infections	7
Acute infections of the urinary tract	7 – 21
Severe infections of the gingiva and periodontal tissues	7

Ask your veterinarian for advice if no improvement of the clinical conditions is observed within 3 days after starting the treatment, although for superficial pyoderma this time should be increased to 7 days, and for deep pyoderma to 14 days.

Cats:

Indication	Duration of treatment (days)
Acute infections of the upper respiratory tract	5

Ask your veterinarian for advice if no improvement of the clinical condition is observed within 3 days after starting the treatment.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Whenever possible, Veraflox should only be used based on susceptibility testing.

Official and local antimicrobial policies should be taken into account when the product is used.

Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.

Use of the product deviating from instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other fluoroquinolones due to the potential for cross-resistance.

Pyoderma occurs mostly secondary to an underlying disease, thus, it is advisable to determine the underlying cause and to treat the animal accordingly.

Veraflox should only be used in severe cases of periodontal disease. Mechanical cleaning of teeth and removal of plaque and calculus or extraction of teeth are prerequisites for a persistent therapeutic effect. In case of gingivitis and periodontitis, Veraflox should only be used as an adjunct to mechanical or surgical periodontal therapy. Only those dogs for which periodontal treatment goals cannot be achieved by mechanical treatment alone should be treated with this veterinary medicinal product.

Pradofloxacin may increase sensitivity of the skin to sunlight. During treatment, animals should therefore not be exposed to excessive sunlight.

Tell your veterinarian if your animal has impaired kidney function. Excretion via kidneys is an important elimination route for pradofloxacin in dogs and, therefore, pradofloxacin should be used with caution in animals with impaired kidney function.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Due to potential harmful effects, the tablets must be kept out of the sight and reach of children.

People with known hypersensitivity to quinolones should avoid any contact with the veterinary medicinal product.

Avoid skin and eye contact with the veterinary medicinal product. Wash hands after use. Do not eat, drink or smoke while handling the veterinary medicinal product.

In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.

Pregnancy, lactation and Fertility:

The safety of Veraflox has not been established during pregnancy and lactation in cats and dogs.

Pregnancy:

Do not use during pregnancy. Pradofloxacin induced eye malformations at foetal and maternal toxic dosages in rats.

Lactation:

Do not use during lactation. Laboratory studies in puppies have shown evidence of arthropathy (damage to the cartilage of joints) after systemic administration of fluoroquinolones.

Fluoroquinolones are known to cross the placenta and to be distributed into milk.

Fertility:

Pradofloxacin has been shown to have no effects on fertility in breeding animals.

Interactions with other medicinal products and other forms of interaction:

There are some medicines that you should not give to your animal during treatment because if given together they might cause serious adverse effects. Tell your veterinarian about all medicines that you intend to give the animal.

Veraflox should not be administered concurrently with antacids or sucralfate (used for gastric acidity), multivitamins or dairy products, as the absorption of Veraflox may be decreased. Further, Veraflox should not be used in combination with non-steroidal anti-inflammatory drugs (NSAIDs; used with pain, fever or inflammation) in animals with a history of seizures because of potential higher sensitivity to seizure formation. The combined use of Veraflox with theophylline (used with chronic respiratory conditions) or digoxin (used with congestive heart failure) should also be avoided because of potentially higher blood levels which could increase the effects of these drugs. Overdose (symptoms, emergency procedures, antidotes):

Vomiting and soft faeces may be symptoms of overdose. No specific antidotes for pradofloxacin (or other fluoroquinolones) are known; therefore, in case of overdose symptomatic treatment should be given.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Medicines should not be disposed of via wastewater or household waste. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2020

15. OTHER INFORMATION

The following pack sizes are available: 7 tablets; 21 tablets; 70 tablets; 140 tablets. Not all pack sizes may be marketed.