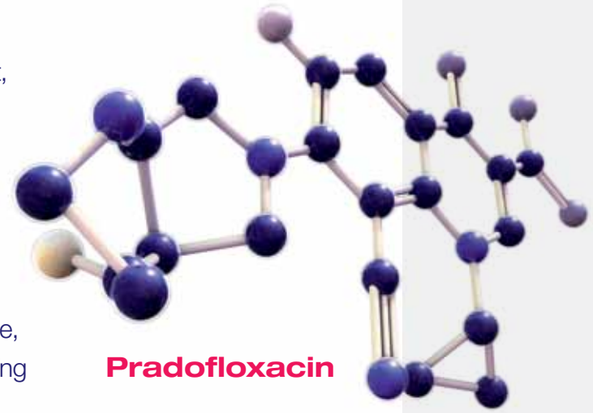
A NEW BREED
OF ANTIBIOTIC

Veraflox®

Veraflox®
Welcome to a new breed of fluoroquinolone

- Veraflox® (pradofloxacin) is an exciting new breed of fluoroquinolone that marks a major leap forward in veterinary antibiotic therapy and patient care.[1] The innovative molecular structure of Veraflox® is specifically engineered to deliver an enhanced spectrum of activity when compared to other fluoroquinolones.[1,2]

- In dogs, Veraflox® provides effective treatment in a once-daily, flavoured tablet, and is the first veterinary fluoroquinolone licensed for the adjunctive treatment of severe periodontal infections.[3,5,6]
- Veraflox® oral suspension has been specifically formulated for cats. It's highly efficacious, and comes in an easy to dose, well-accepted palatable formulation offering accurate dosing.[7-10,13]

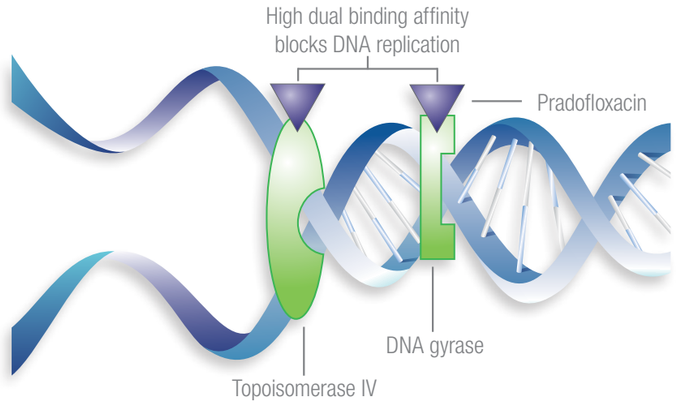


Pradofloxacin

Enhanced spectrum of antimicrobial activity when compared to other fluoroquinolones[2]

Veraflox® rapidly fights bacteria with high-activity dual molecular targeting[12]

- The dual-targeting mechanism means that therapeutic doses of Veraflox® are capable of binding with high affinity to both bacterial DNA gyrase and topoisomerase IV.[11]
- Inhibition of these target enzymes not only results in enhanced bactericidal activity but also reduces the potential for the development of resistant organisms.[5,11,12]
- In addition, Veraflox has been shown to be effective against both actively replicating and dormant bacteria.[12]

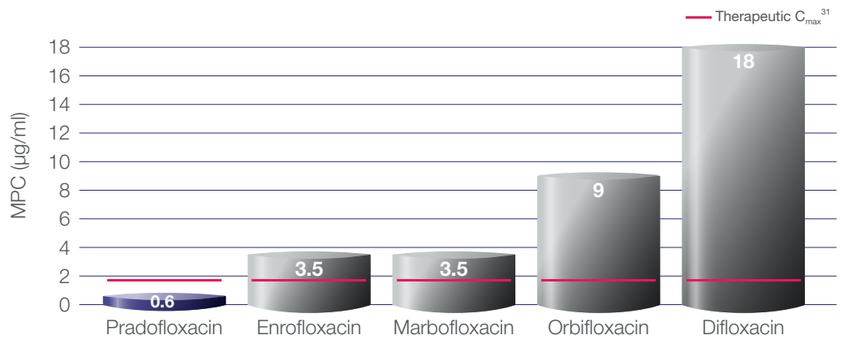


Dual Molecular Targeting

Veraflox® and the MPC

- Traditionally, the amount of antibiotic needed to combat bacterial infection has been determined by the Minimum Inhibitory Concentration (MIC); this represents the lowest concentration of an antimicrobial drug needed to inhibit visible growth of a bacterial isolate.
- In substantial bacterial populations, spontaneous mutations can occur; this phenomenon cannot be prevented, however these mutant cells may be less susceptible to the antibiotic being used, with the result that the resistant strain is selected for and will multiply.[28,29]
- To address this problem, the concept of the Mutant Prevention Concentration (MPC) has been developed, wherein a concentration of drug is used that will inhibit not only the susceptible strains but also the mutant ones.
- Antimicrobial dosing based on MIC and not MPC could lead to underdosing and the selection of resistant mutant strains; by achieving drug concentrations that exceed MPC, one reduces the potential for selection of resistant bacteria.[28-30]
- With the lowest available MIC and MPC fluoroquinolone values overall (see below), Veraflox fights both susceptible and first-step resistant bacteria at therapeutic concentrations.[11]

Comparative MPC values of veterinary fluoroquinolones against *Staphylococcus* sp. in relation to serum drug levels reached in dogs[11]



+ CATS

Veraflox® for cats is available as a tablet and oral suspension, and is licensed for the treatment of the following conditions:

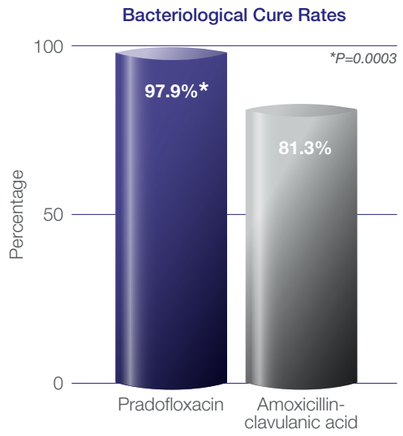
- Upper respiratory tract infections†✣◆
- Wound infections†◆
- Abscesses†◆

Upper respiratory tract infections (URTIs)

Severe URTI with mucopurulent nasal discharge

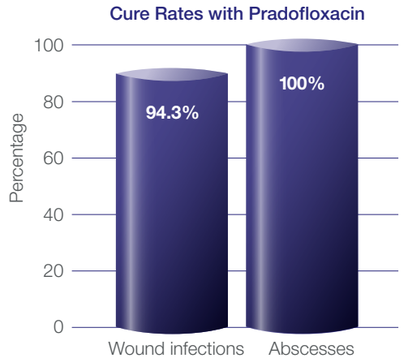
E. coli

- Bacteria isolated from feline URTIs – *Pasteurella multocida*, *Escherichia coli* and *Staphylococcus intermedius* – were found to be highly susceptible to pradofloxacin.[8]
- Veraflox® reaches markedly higher concentrations in the saliva and tear fluid of cats than in serum - which is favourable for penetration into infected upper respiratory tract tissues.[7]
- Veraflox® demonstrated superior bacteriological resolution of feline URTI compared with amoxicillin-clavulanic acid.[8]



Wound infections and abscesses

- Veraflox® demonstrated a 94.3% cure rate for wound infections.[9]
- Veraflox® demonstrated a 100% cure rate for abscesses.[9]



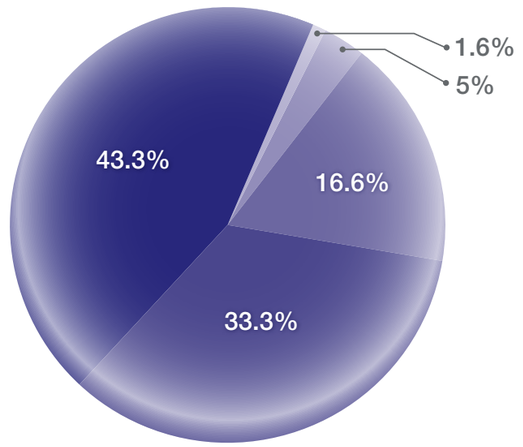
Veraflox® oral suspension is bound to a fine-grained ion exchange agent that allows the antibiotic to pass taste buds undetected, improving palatability

- Once daily oral suspension with breakthrough taste-masking technology.
- Easy to administer, and mess-free syringe with both ml and kg graduations, makes dosing more accurate.
- The palatable formulation optimises owner compliance.[10]

Drawing off the oral suspension

Veraflox® oral suspension is highly palatable and easy to administer[13]

Veraflox® was assessed for palatability according to the following rating system in controlled studies.



Palatability study scoring key

- 5 = administered without any difficulties
- 4 = easy to administer
- 3 = moderate refusal
- 2 = very difficult to administer
- 1 = not accepted at all

Safety information

- The safety of Veraflox® was assessed in a series of clinical field studies involving more than 700 dogs and cats.[4,14-21]
  - Adverse events were mild and transient and comparable to control products.
  - Observed signs resolved without treatment.
- Extensive ocular safety testing demonstrated that pradofloxacin had no adverse retinal effects at 10 times the recommended dosage in cats.[22]
- Veraflox® was well-tolerated in kittens as young as six weeks of age, with no adverse ocular effects or effects on articular cartilage observed at elevated dosages.[23]

Safety data from clinical field studies**

Adverse events in cats

Adverse event	Number of cats affected	Percentage of cats affected
Diarrhoea	12	2.5%
Vomiting	6	1.3%
Salivation	2	0.4%
Anorexia	2	0.4%

** n = 474 cats

+ DOGS

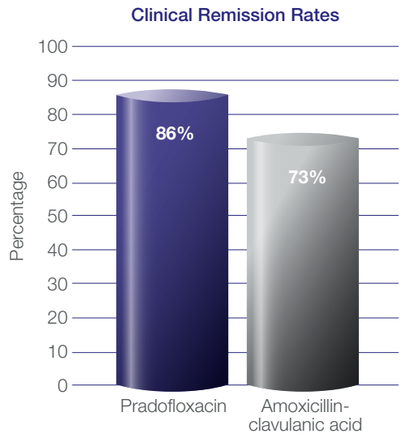
Veraflox® for dogs is available as a once-daily flavoured tablet and is licensed for the treatment of the following conditions:

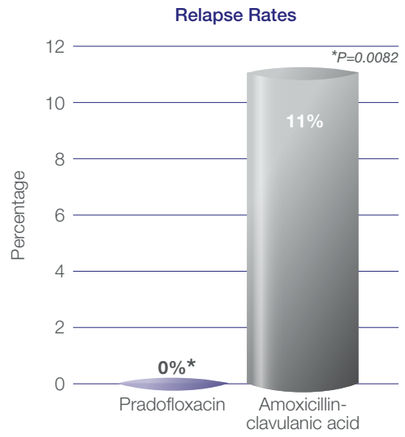
- Superficial and deep pyoderma◆
- Wound infections◆
- Urinary tract infections◆
- Adjunctive therapy for severe periodontal infections◆

Folliculitis and furunculosis on dog's chin

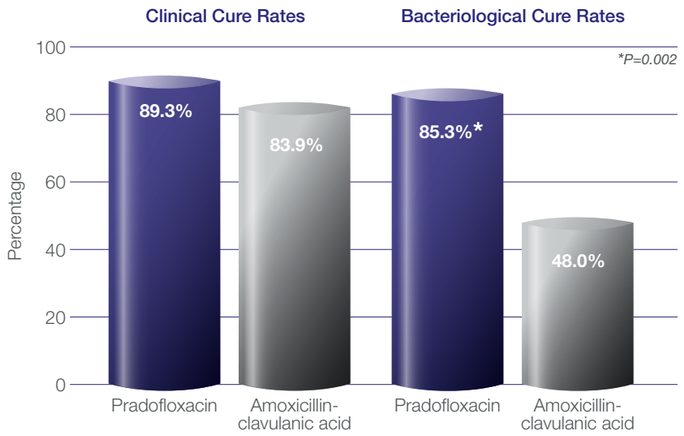
Deep pyoderma

- 86% of dogs treated for the difficult condition of deep pyoderma displayed rapid clinical remission.[24]
- Veraflox® proved significantly more effective than amoxicillin-clavulanic acid at preventing a relapse of pyoderma; two weeks after cessation of therapy, no relapses of deep pyoderma were observed, following treatment with Veraflox®.[24]





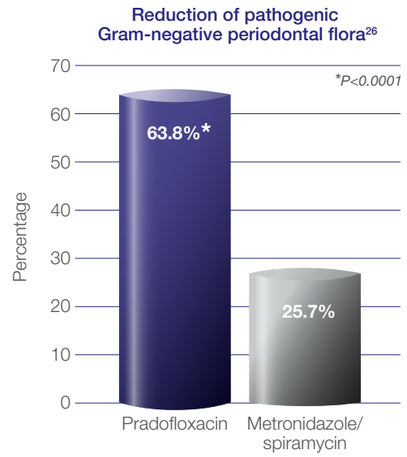
Urinary tract infections

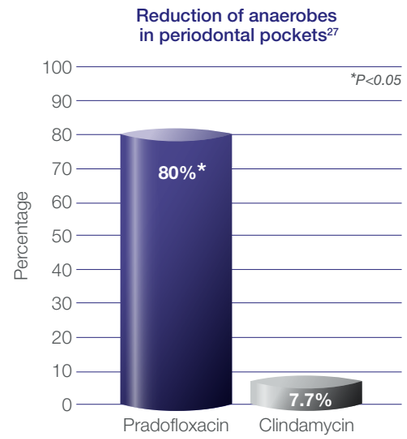


- Veraflox® achieved an 89% clinical cure in dogs with UTIs.[25]
- Veraflox® was significantly more effective in achieving a bacteriological cure than amoxicillin-clavulanic acid.[25]

Periodontal infections

- Veraflox® is the first and only veterinary fluoroquinolone licensed as an adjunctive treatment for severe infections of the gingiva and periodontal tissues caused by susceptible strains of anaerobic organisms.[3]
- This activity against anaerobes makes Veraflox® a strong choice for the adjunctive treatment of this important condition.
- Veraflox® is very effective at eliminating anaerobic bacteria that play a major role in aggressive bone destruction in periodontal disease, including *Porphyromonas* spp and *Prevotella* spp.[6]





- Veraflox® proved clinically superior in the reduction of Gram-negative bacteria compared with metronidazole/spiramycin.[26]
- Veraflox® reduced the numbers of periodontal pathogens, allowing the re-establishment of healthy flora.[26]
- Veraflox® was significantly better than clindamycin at reducing numbers of anaerobic bacteria.[27]
- Veraflox® demonstrated beneficial effects on pocket depth, loss of attachment, and bleeding on probing.[26,27]

Severe periodontal infection

Porphyromonas gingivalis

Severe periodontal infection

Safety information

- The safety of Veraflox® was assessed in a series of clinical field studies involving more than 700 dogs and cats.[4,14-21]
  - Adverse events were mild and transient and comparable to control products.
  - Observed signs resolved without treatment.

Safety data from clinical field studies**

Adverse events in dogs		
Adverse event	Number of dogs affected	Percentage of dogs affected
Diarrhoea	17	4.3%
Vomiting	13	3.3%
Tiredness/sleepiness	5	1.3%
Polydipsia	5	1.3%

** n = 395 dogs

+ REFERENCES, DOSAGE GUIDES AND DATA SHEETS

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† The oral suspension is indicated for the treatment of acute infections of the upper respiratory tract, wound infections and abscesses.

✣ The 15 mg tablet is indicated for the treatment of feline upper respiratory tract infections only.

◆ Infections caused by susceptible strains of named bacterial species.

Use Medicines Responsibly (www.noah.co.uk/responsible)

Veraflox® 15 mg tablets contain 15 mg Pradofloxacin. Veraflox® 60 mg tablets contain 60 mg Pradofloxacin. Veraflox® 120 mg tablets contain 120 mg Pradofloxacin.

Content: Each tablet contains: Pradofloxacin 15 mg; Pradofloxacin 60 mg; Pradofloxacin 120 mg.

Dose: 3 mg/kg b.w. once daily.

Indications for use
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.
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*).

Contraindications: Do not use in animals with known hypersensitivity to fluoroquinolones.
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.
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.

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

Veraflox® 25 mg/ml oral suspension for cats contains 25 mg/ml Pradofloxacin.

Content: Each ml contains: Pradofloxacin 25 mg.

Dose: 5 mg/kg b.w. once daily.

Indications for use: 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*), wound infections and abscesses caused by susceptible strains of *Pasteurella multocida* and the *Staphylococcus intermedius* group (including *S. pseudintermedius*).

Contraindications: Do not use in cats with known hypersensitivity to fluoroquinolones. 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.

Adverse reactions: Mild transient gastro-intestinal disturbances including vomiting have been observed in rare cases.

Keep out of the reach and sight of children.

For information on Special warnings for each target species, Special precautions for use, Adverse reactions and Interactions with other medicinal products and other forms of interaction, please see the published SPCs.

Please refer to the appropriate datasheet, further information is available upon request.

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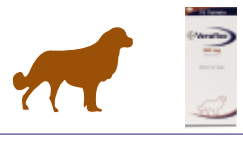
Optimise your patient care with Veraflox®

- Specifically engineered to deliver an enhanced spectrum of antimicrobial activity (including Gram-positive and anaerobic bacteria) when compared to other fluoroquinolones.[1,2]
- In dogs, Veraflox® provides effective treatment in a once-daily, flavoured tablet, and is the first fluoroquinolone licensed as an adjunctive treatment for severe periodontal infections.[3,5,6]
- Veraflox® oral suspension has been specifically formulated for cats – it's highly efficacious, and comes in an easy to dose, well-accepted, palatable oral formulation that offers accurate dosing.[7-10]

Veraflox® is formulated for flexibility, palatability and compliance

Palatable oral suspension		Dosage	Dose frequency
	Veraflox® 25 mg/ml oral suspension for cats	5 mg/kg	1 x daily 1 ml for 4 – 5 kg bodyweight cat
Meat-flavoured tablets			
	Veraflox® 15 mg tablets for dogs and cats	3 mg/kg	1 x daily 1 tablet for 3.5 – 5 kg bodyweight cat / dog
	Veraflox® 60 mg tablets for dogs	3 mg/kg	1 x daily 1 tablet for 15 – 20 kg bodyweight dog
	Veraflox® 120 mg tablets for dogs	3 mg/kg	1 x daily 1 tablet for 30 – 40 kg bodyweight dog

A data sheet for each formulation is supplied with this brochure

Veraflox®

Veraflox®

THIS BROCHURE CONTAINS:

1 x Veraflox® Dosage Guide
1 x Veraflox® Tablets Data Sheet
1 x Veraflox® Oral Suspension Data Sheet

Please contact your Bayer representative for further information or for replacement dosage guides.