

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 15 mg tablets for dogs and cats

Veraflox 60 mg tablets for dogs

Veraflox 120 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Pradofloxacin	15 mg
Pradofloxacin	60 mg
Pradofloxacin	120 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Cellulose, microcrystalline
Povidone
Magnesium stearate
Silica, colloidal anhydrous
Artificial beef flavour
Croscarmellose sodium

Brownish single-scored tablets that can be divided into two equal doses, with “P15”, “P60” or “P120” respectively, on one side.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats.

3.2 Indications for use for each target species

Dogs:

Treatment of:

- wound infections caused by strains of the *Staphylococcus intermedius* group (including *S. pseudintermedius*),
- superficial and deep pyoderma caused by strains of the *Staphylococcus intermedius* group (including *S. pseudintermedius*),

- acute urinary tract infections caused by 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 strains of anaerobic organisms, for example *Porphyromonas* spp. and *Prevotella* spp. (see section 3.5 Special precautions of use).

Cats:

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

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance 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 3.7).

Cats:

Do not use in kittens aged less than 6 weeks.

Pradofloxacin has no effects on the developing cartilage of kittens of 6 weeks of age and older.

Do not use in cats with persisting articular cartilage lesions, since 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 3.7).

3.4 Special warnings

Cross-resistance has been shown between pradofloxacin and other fluoroquinolones. Use of pradofloxacin should be carefully considered when susceptibility testing has shown resistance to fluoroquinolones because its effectiveness may be reduced.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of

susceptibility of the target pathogens at local/regional level. Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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

This veterinary medicinal product 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, the veterinary medicinal product 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.

Excretion via kidneys is an important elimination route for pradofloxacin in dogs. As for other fluoroquinolones, the renal excretion rate of pradofloxacin may be decreased in dogs with impaired kidney function and, therefore, pradofloxacin should be used with caution in such animals.

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

People with known hypersensitivity to quinolones should avoid 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 immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Digestive tract disorder (e.g. Vomiting) ¹
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¹ Mild and transient

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy:

Do not use during the whole or part of the pregnancy.

Laboratory studies in rats have shown evidence of pradofloxacin induced eye malformations at foetotoxic and maternotoxic doses.

Lactation:

Do not use during lactation. Laboratory studies in puppies have shown evidence of arthropathy 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.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration with metal cations, such as those contained in antacids or sucralfate made with magnesium hydroxide or aluminium hydroxide, or multivitamins containing iron or zinc, and dairy products containing calcium, has been reported to decrease the bioavailability of fluoroquinolones. Therefore, the veterinary medicinal product should not be administered concurrently with antacids, sucralfate, multivitamins or dairy products, as absorption of the veterinary medicinal product may be decreased.

Further, fluoroquinolones should not be used in combination with non-steroidal anti-inflammatory drugs (NSAIDs) in animals with a history of seizures because of potential pharmacodynamic interactions in the CNS. The combination of fluoroquinolones with theophylline could increase the plasma levels of theophylline by altering its metabolism and thus should be avoided. The combined use of fluoroquinolones with digoxin should also be avoided because of potentially increased oral bioavailability of digoxin.

3.9 Administration routes and dosage

Oral use.

The recommended dose is 3 mg/kg bodyweight of pradofloxacin once daily. To ensure a correct dosage, body weight should be determined as accurately as possible. Due to the available tablet sizes the resulting dose range is 3 to 4.5 mg/kg bodyweight according to the following tables.

When the dose requires a half tablet to be used the remaining portion should be given at the next administration.

Dogs:

Bodyweight (kg)	Strength and number of tablets		
	15 mg	60 mg	120 mg
>3.4 – 5	1		
>5 – 7.5	1½		
>7.5 – 10	2		
>10 – 15	3		
>15 – 20		1	

>20 – 30		1½	
>30 – 40			1
>40 – 60			1½
>60 – 80			2

Cats:

Bodyweight (kg)	Strength and number of tablets
	15 mg
>3.4 – 5	1
>5 – 7.5	1½
>7.5 – 10	2

Duration of treatment

The duration of the treatment depends on the nature and severity of the infection and on the response to treatment. For most infections the following treatment courses will be sufficient:

Dogs:

Indication	Duration of treatment (days)
Skin infections:	
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

The treatment should be re-considered if no improvement of the clinical conditions is observed within 3 days, or in cases of superficial pyoderma 7 days, and in cases of deep pyoderma 14 days, after starting the treatment.

Cats:

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

The treatment should be re-considered if no improvement of the clinical condition is observed within 3 days after starting the treatment.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No specific antidotes for pradofloxacin (or other fluoroquinolones) are known, therefore, in case of overdose, symptomatic treatment should be given.

Intermittent vomiting and soft faeces were observed in dogs after repeated oral administration of 2.7 times the maximum recommended dose.

Infrequent vomiting was observed in cats after repeated oral administration of 2.7 times the maximum recommended dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01MA97

4.2 Pharmacodynamics

Mode of action

The primary mode of action of the fluoroquinolones involves interaction with enzymes essential for major DNA functions such as replication, transcription and recombination. The primary targets for pradofloxacin are the bacterial DNA gyrase and topoisomerase IV enzymes. Reversible association between pradofloxacin and DNA gyrase or DNA topoisomerase IV in the target bacteria results in inhibition of these enzymes and rapid death of the bacterial cell. The rapidity and extent of bacterial killing are directly proportional to the drug concentration.

Antibacterial Spectrum

Although pradofloxacin has *in vitro* activity against a wide range of Gram-positive and Gram-negative organisms, including anaerobic bacteria, this veterinary medicinal product should only be used for the approved indications (see section 3.2) and in accordance with the prudent use recommendations in section 3.5 of this Summary of Product Characteristics (SPC).

MIC-Data

Dogs:

Bacterial species	Number of strains	MIC ₅₀ (mcg/ml)	MIC ₉₀ (mcg/ml)	MIC range (mcg/ml)
<i>Staphylococcus intermedius</i> group (including <i>S. pseudintermedius</i>) - skin and soft tissue infections ²	344	0.03	1	0.008-4
<i>Staphylococcus intermedius</i> group (including <i>S. pseudintermedius</i>) – urinary tract infections (UTI) ¹	117	0.03	0.5	0.008-4
<i>Escherichia coli</i> – urinary tract infections (UTI) ¹	324	0.015	0.12	0.004-32

¹ Data collected between 2017-2018

² Data collected between 2021-2022

The bacteria were isolated from clinical cases in Belgium, Czech Republic, France, Germany, Hungary, Italy, the Netherlands, Poland, Spain, Sweden, Switzerland and UK.

Clinical breakpoints established by CLSI in 2024 (7th edition) for pradofloxacin isolated in dogs for skin and (lower) urinary tract infections are as follows:

Organism	Minimum Inhibitory Concentration breakpoints of pradofloxacin (mcg/ml)		
	susceptible	intermediate	resistant
<i>E. coli</i>	≤0.25	0.5-1	≥2
<i>S. pseudintermedius</i>	≤0.25	0.5-1	≥2

Cats:

Bacterial species	Number of strains	MIC ₅₀ (mcg/ml)	MIC ₉₀ (mcg/ml)	MIC range (mcg/ml)
<i>Pasteurella multocida</i> - respiratory tract infections ¹	64	0.008	0.008	0.004-0.03
<i>Escherichia coli</i> – respiratory tract infections (RTI) ¹	22	0.015	4	0.008-8
<i>Staphylococcus intermedius</i> group (including <i>S. pseudintermedius</i>) – respiratory tract infections (RTI) ¹	25	0.12	2	0.008-4

¹ Data collected between 2017-2018

The bacteria were isolated from clinical cases in Belgium, Czech Republic, France, Germany, Hungary, Italy, the Netherlands, Poland, Spain, Sweden, Switzerland and UK.

Clinical breakpoints established by CLSI in 2024 (7th edition) for pradofloxacin in cats for respiratory tract infections are:

Organism	Minimum Inhibitory Concentration breakpoints of pradofloxacin (mcg/ml)		
	susceptible	intermediate	resistant
<i>E. coli</i>	≤0.25	0.5-1	≥2
<i>S. pseudintermedius</i>	≤0.25	0.5-1	≥2

Types and Mechanisms of Resistance

Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

4.3 Pharmacokinetics

In laboratory studies the bioavailability of pradofloxacin was reduced in fed dogs and cats compared to fasted animals. However, in the clinical studies feeding did not reveal any impact on the treatment effect.

Dogs:

After oral administration of the therapeutic dose to dogs, pradofloxacin is rapidly (T_{\max} of 2 hours) and almost completely (approximately 100%) absorbed reaching peak concentrations of 1.6 mg/l.

A linear relationship between pradofloxacin serum concentrations and the administered dose is observed in dogs within a tested dose range of 1 to 9 mg/kg body weight. Long-term daily treatment has no impact on the pharmacokinetic profile, with an accumulation index of 1.1. *In vitro* plasma protein binding is low (35%). The high volume of distribution (V_d) > 2 l/kg bodyweight indicates good tissue penetration. Pradofloxacin concentrations in skin homogenates of dogs exceed those in serum by up to seven times.

Pradofloxacin is eliminated from serum with a terminal half-life of 7 hours. Major elimination pathways are glucuronidation as well as renal excretion. Pradofloxacin is cleared from the body at 0.24 l/h/kg. Approximately 40% of the administered product is excreted unchanged via the kidneys.

Cats:

In cats, absorption of orally administered pradofloxacin at the therapeutic dose is rapid reaching peak concentrations of 1.2 mg/l within 0.5 hours. The bioavailability of the tablet is at least 70%. Repeated dosing shows no impact on the pharmacokinetic profile (accumulation index = 1.0). *In vitro* plasma protein binding is low (30%). The high volume of distribution (V_d) > 4 l/kg body weight indicates good tissue penetration.

Pradofloxacin is eliminated from serum with a terminal half-life of 9 hours. The major elimination pathway in cats is glucuronidation. Pradofloxacin is cleared from the body at 0.28 l/h/kg.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Folding cartons containing aluminium blister packs. One blister contains 7 tablets.
The following pack sizes are available: 7, 21, 70 or 140 tablets.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Animal Health GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/107/001-012

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 12 April 2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 25 mg/ml oral suspension for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Pradofloxacin 25 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Sorbic acid (E200)	2 mg
Amberlite IRP 64	
Ascorbic acid	
Xanthan gum	
Propylene glycol	
Vanilla flavour	
Purified water	

Yellowish to beige suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

Treatment of:

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

3.3 Contraindications

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

Do not use in kittens aged less than 6 weeks.

Pradofloxacin has no effects on the developing cartilage of kittens of 6 weeks of age and older.
Do not use in cats with persisting articular cartilage lesions, since 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 3.7).

3.4 Special warnings

Cross-resistance has been shown between pradofloxacin and other fluoroquinolones. Use of pradofloxacin should be carefully considered when susceptibility testing has shown resistance to fluoroquinolones because its effectiveness may be reduced.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies. An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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

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

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. In case of accidental contact with the eyes, wash immediately with water. In case of contact with the skin, rinse off with water. 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Digestive tract disorder (e.g. Vomiting) ¹
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¹ Mild and transient

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of this veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy:

Do not use during the whole or part of pregnancy. Laboratory studies in rats have shown evidence of pradofloxacin induced eye malformations at foetotoxic and maternotoxic dosages.

Lactation:

Do not use during lactation since there are no data on pradofloxacin in kittens aged less than 6 weeks. 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.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration with metal cations such as those contained in antacids or sucralfate made with magnesium hydroxide or aluminium hydroxide, or multivitamins containing iron or zinc, and dairy products containing calcium, has been reported to decrease the bioavailability of fluoroquinolones. Therefore, the veterinary medicinal product should not be administered concurrently with antacids, sucralfate, multivitamins or dairy products, as absorption of the veterinary medicinal product may be decreased.

Further, fluoroquinolones should not be used in combination with non-steroidal anti-inflammatory drugs (NSAIDs) in animals with a history of seizures because of potential pharmacodynamic interactions in the CNS. The combination of fluoroquinolones with theophylline could increase the plasma levels of theophylline by altering its metabolism and thus should be avoided. The combined use of fluoroquinolones with digoxin should also be avoided because of potentially increased oral bioavailability of digoxin.

3.9 Administration routes and dosage

Oral use.

The recommended dose is 5 mg/kg bodyweight of pradofloxacin once daily. To ensure a correct dosage, body weight should be determined as accurately as possible. Due to the graduation of the syringe the resulting dose range is 5 to 7.5 mg/kg bodyweight according to the following table:

Bodyweight (kg)	Dose of oral suspension to be given (ml)
>0.67 - 1	0.2
>1 - 1.5	0.3
>1.5 - 2	0.4
>2 - 2.5	0.5
>2.5 - 3	0.6
>3 - 3.5	0.7
>3.5 - 4	0.8
>4 - 5	1
>5 - 6	1.2
>6 - 7	1.4
>7 - 8	1.6
>8 - 9	1.8
>9 - 10	2

Duration of treatment

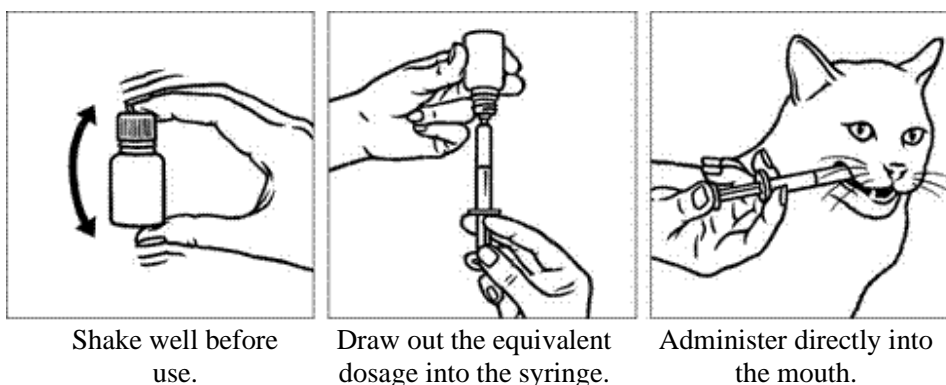
The duration of the treatment depends on the nature and severity of the infection and on the response to treatment. For most infections the following treatment courses will be sufficient:

Indication	Duration of treatment (days)
Wound infections and abscesses	7
Acute infections of the upper respiratory tract	5

The treatment should be reconsidered if no improvement of the clinical condition is observed within 3 days after starting the treatment.

Method of administration

To facilitate accurate dosing, the 15 ml bottle of Veraflox oral suspension is supplied with a 3 ml oral dosing syringe (graduation: 0.1 to 2 ml).



To avoid cross-contamination, the same syringe should not be used for different animals. Thus, one syringe should only be used for one animal. After administration, the syringe should be cleaned with tap water and stored in the carton box together with the veterinary medicinal product.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No specific antidotes for pradofloxacin (or other fluoroquinolones) are known, therefore, in case of overdose, symptomatic treatment should be given.

Intermittent vomiting was observed after repeated oral administration of 1.6 times the maximum recommended dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01MA97

4.2 Pharmacodynamics

Mode of Action

The primary mode of action of the fluoroquinolones involves interaction with enzymes essential for major DNA functions such as replication, transcription and recombination. The primary targets for pradofloxacin are the bacterial DNA gyrase and topoisomerase IV enzymes. Reversible association between pradofloxacin and DNA gyrase or DNA topoisomerase IV in the target bacteria results in inhibition of these enzymes and rapid death of the bacterial cell. The rapidity and extent of bacterial killing are directly proportional to the drug concentration.

Antibacterial Spectrum

Although pradofloxacin has *in vitro* activity against a wide range of Gram-positive and Gram-negative organisms, including anaerobic bacteria, this veterinary medicinal product should only be used for the approved indications (see section 3.2) and in accordance with the prudent use recommendations in section 3.5 of this Summary of Product Characteristics (SPC).

MIC-Data

Bacterial species	Number of strains	MIC ₅₀ (mcg/ml)	MIC ₉₀ (mcg/ml)	MIC range (mcg/ml)
<i>Pasteurella multocida</i> - respiratory tract infections (RTI) ¹	64	0.008	0.008	0.004-0.03
<i>Pasteurella multocida</i> – wound infections ²	42	0.008	0.008	0.004 – 0.03
<i>Escherichia coli</i> – respiratory tract infections (RTI) ¹	22	0.015	4	0.008-8

<i>Staphylococcus intermedius</i> group (including <i>S. pseudintermedius</i>) – respiratory tract infections (RTI) ¹	25	0.12	2	0.008-4
<i>Staphylococcus intermedius</i> group (including <i>S. pseudintermedius</i>) – wound infections ²	20	0.03	2	0.15 – 2

¹ Data collected between 2017-2018

² Data collected between 2021-2022

The bacteria were isolated from clinical cases in Belgium, Czech Republic, France, Germany, Hungary, Italy, the Netherlands, Poland, Spain, Sweden, Switzerland and UK.

Clinical breakpoints established by CLSI in 2024 (7th edition) for pradofloxacin in cats for respiratory tract infections are:

Organism	Minimum Inhibitory Concentration breakpoints of pradofloxacin (mcg/ml)		
	susceptible	intermediate	resistant
<i>E. coli</i>	≤0.25	0.5-1	≥2
<i>S. pseudintermedius</i>	≤0.25	0.5-1	≥2

Types and Mechanisms of Resistance

Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

4.3 Pharmacokinetics

In laboratory studies the bioavailability of pradofloxacin was reduced in fed cats compared to fasted animals. However, in the clinical studies feeding did not reveal any impact on the treatment effect.

After oral administration of the veterinary medicinal product to cats at the recommended therapeutic dose, absorption of pradofloxacin is rapid, reaching peak concentrations of 2.1 mg/l within 1 hour. The bioavailability of the veterinary medicinal product is at least 60%. Repeated dosing shows no impact on the pharmacokinetic profile, (accumulation index = 1.2). *In vitro* plasma protein binding is low (30%). The high volume of distribution (V_d) > 4 l/kg body weight indicates good tissue penetration. Pradofloxacin is eliminated from serum with a terminal half-life of 7 hours. The major elimination pathway in cats is glucuronidation. Pradofloxacin is cleared from the body at 0.28 l/h/kg.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

Shelf life after first opening the immediate packaging: 3 months

5.3 Special precautions for storage

Store in the original container.

Keep the bottle tightly closed.

5.4 Nature and composition of immediate packaging

Folding carton containing a white high-density polyethylene (HDPE) bottle with a polyethylene adapter and a child-resistant closure.

Pack sizes: 15 ml bottle with a 3 ml polypropylene oral dosing syringe (graduation: 0.1 to 2 ml) and 30 ml bottle.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Animal Health GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/107/013-014

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 12 April 2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX - Tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 15 mg tablets
Veraflox 60 mg tablets
Veraflox 120 mg tablets

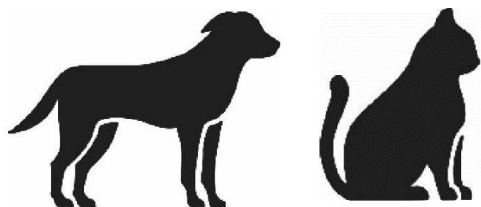
2. STATEMENT OF ACTIVE SUBSTANCES

15 mg pradofloxacin
60 mg pradofloxacin
120 mg pradofloxacin

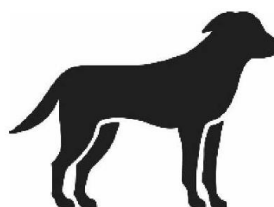
3. PACKAGE SIZE

7 tablets
21 tablets
70 tablets
140 tablets

4. TARGET SPECIES



{ Veraflox 15 mg }



{ Veraflox 60 mg; Veraflox 120 mg }

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.


11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco 

14. MARKETING AUTHORISATION NUMBERS

EU/2/10/107/001 (15 mg pradofloxacin; 7 tablets)
EU/2/10/107/002 (15 mg pradofloxacin; 21 tablets)
EU/2/10/107/003 (15 mg pradofloxacin; 70 tablets)
EU/2/10/107/004 (15 mg pradofloxacin; 140 tablets)
EU/2/10/107/005 (60 mg pradofloxacin; 7 tablets)
EU/2/10/107/006 (60 mg pradofloxacin; 21 tablets)
EU/2/10/107/007 (60 mg pradofloxacin; 70 tablets)
EU/2/10/107/008 (60 mg pradofloxacin; 140 tablets)
EU/2/10/107/009 (120 mg pradofloxacin; 7 tablets)
EU/2/10/107/010 (120 mg pradofloxacin; 21 tablets)
EU/2/10/107/011 (120 mg pradofloxacin; 70 tablets)
EU/2/10/107/012 (120 mg pradofloxacin; 140 tablets)

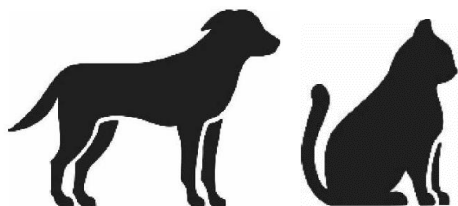
15. BATCH NUMBER

Lot {number}

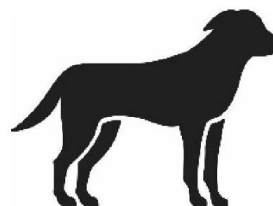
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox



{ Veraflox 15 mg }



{ Veraflox 60 mg; Veraflox 120 mg }

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

15 mg pradofloxacin
60 mg pradofloxacin
120 mg pradofloxacin

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX - Oral Suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 25 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

25 mg/ml pradofloxacin

3. PACKAGE SIZE

15 ml with 3 ml oral dosing syringe
30 ml

4. TARGET SPECIES



Cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container.
Keep the bottle tightly closed.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.


11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco 

14. MARKETING AUTHORISATION NUMBERS

EU/2/10/107/013 (15 ml bottle)
EU/2/10/107/014 (30 ml bottle)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

15 ml bottle

30 ml bottle

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 3 months.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Veraflox 15 mg tablets for dogs and cats

Veraflox 60 mg tablets for dogs

Veraflox 120 mg tablets for dogs

2. Composition

Each tablet contains:

Active substance:

Pradofloxacin	15 mg
Pradofloxacin	60 mg
Pradofloxacin	120 mg

Brownish single-scored tablets that can be divided into two equal doses, with “P15”, “P60” or “P120” respectively, on one side.

3. Target species

Dogs, cats.



4. Indications for use

Dogs:

Treatment of:

- wound infections caused by strains of the *Staphylococcus intermedius* group (including *S. pseudintermedius*),
- superficial and deep pyoderma caused by strains of the *Staphylococcus intermedius* group (including *S. pseudintermedius*),
- acute urinary tract infections caused by 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 strains of anaerobic organisms, for example *Porphyromonas* spp. and *Prevotella* spp. (see section “Special precautions for safe use in the target species”).

Cats:

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

5. Contraindications

Do not use in cases of hypersensitivity to the active substance 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:

Do not use in kittens aged less than 6 weeks.

Pradofloxacin has no effects on the developing cartilage of kittens of 6 weeks of age and older.

Do not use in cats with persisting articular cartilage lesions, since 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. Special warnings

Special warnings:

Cross-resistance has been shown between pradofloxacin and other fluoroquinolones. Use of pradofloxacin should be carefully considered when susceptibility testing has shown resistance to fluoroquinolones because its effectiveness may be reduced.

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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

This veterinary medicinal product 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, the veterinary medicinal product 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.

Excretion via kidneys is an important elimination route for pradofloxacin in dogs. As for other fluoroquinolones, the renal excretion rate of pradofloxacin may be decreased in dogs with impaired kidney function and, therefore, pradofloxacin should be used with caution in such animals.

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

People with known hypersensitivity to quinolones should avoid 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 immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

The safety of this veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy:

Do not use during the whole or part of the pregnancy.

Laboratory studies in rats have shown evidence of pradofloxacin induced eye malformations at foetotoxic and maternotoxic doses.

Lactation:

Do not use during lactation. Laboratory studies in puppies have shown evidence of arthropathy 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.

Interaction with other medicinal products and other forms of interaction:

Concurrent administration with metal cations, such as those contained in antacids or sucralfate made with magnesium hydroxide or aluminium hydroxide, or multivitamins containing iron or zinc, and dairy products containing calcium, has been reported to decrease the bioavailability of fluoroquinolones. Therefore, the veterinary medicinal product should not be administered concurrently with antacids, sucralfate, multivitamins or dairy products, as absorption of the veterinary medicinal product may be decreased.

Further, fluoroquinolones should not be used in combination with non-steroidal anti-inflammatory drugs (NSAIDs) in animals with a history of seizures because of potential pharmacodynamic interactions in the CNS. The combination of fluoroquinolones with theophylline could increase the plasma levels of theophylline by altering its metabolism and thus should be avoided. The combined use of

fluoroquinolones with digoxin should also be avoided because of potentially increased oral bioavailability of digoxin.

Overdose:

No specific antidotes for pradofloxacin (or other fluoroquinolones) are known, therefore, in case of overdose, symptomatic treatment should be given.

Intermittent vomiting and soft faeces were observed in dogs after repeated oral administration of 2.7 times the maximum recommended dose. Infrequent vomiting was observed in cats after repeated oral administration of 2.7 times the maximum recommended dose.

7. Adverse events

Dogs and cats:

Rare (1 to 10 animals / 10 000 animals treated):
Digestive tract disorder (e.g. Vomiting) ¹

¹ Mild and transient

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Oral use.

The recommended dose is 3 mg/kg bodyweight of pradofloxacin once daily. To ensure a correct dosage, body weight should be determined as accurately as possible.

Due to the available tablet sizes the resulting dose range is 3 to 4.5 mg/kg bodyweight according to the following tables.

Dogs:

Bodyweight (kg)	Strength and Number of tablets		
	15 mg	60 mg	120 mg
>3.4 – 5	1		
>5 – 7.5	1½		
>7.5 – 10	2		
>10 – 15	3		
>15 – 20		1	
>20 – 30		1½	
>30 – 40			1
>40 – 60			1½

>60 – 80			2
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Cats:

Bodyweight (kg)	Strength and Number of tablets
	15 mg
>3.4 – 5	1
>5 – 7.5	1½
>7.5 – 10	2

9. Advice on correct administration

When the dose requires a half tablet to be used the remaining portion should be given at the next administration.

Duration of treatment

The medication should be administered for as long as advised by your veterinarian.

The duration of the treatment depends on the nature and severity of the infection and on the response to treatment. For most infections the following treatment courses will be sufficient:

Dogs:

Indication	Duration of treatment (days)
Skin infections:	
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

The treatment should be re-considered if no improvement of the clinical conditions is observed within 3 days, or in cases of superficial pyoderma 7 days, and in cases of deep pyoderma 14 days, after starting the treatment.

Cats:

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

The treatment should be re-considered if no improvement of the clinical condition is observed within 3 days after starting the treatment.

Do not use veterinary medicinal product if you notice visible signs of packaging deterioration.

10. Withdrawal periods

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 carton and the blister after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/10/107/001-012

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

15. Date on which the package leaflet was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco Animal Health GmbH, Alfred-Nobel-Strasse 50, 40789 Monheim, Germany

België/Belgique/Belgien
Tél/Tel: +32 33000338

Lietuva
Tel: +372 8840389

PV.BEL@elancoah.com

Република България
Тел: +48 221047815
PV.BGR@elancoah.com

Česká republika
Tel: +420 228880231
PV.CZE@elancoah.com

Danmark
Tlf: +45 78775477
PV.DNK@elancoah.com

Deutschland
Tel: +49 32221852372
PV.DEU@elancoah.com

Eesti
Tel: +372 8807513
PV.EST@elancoah.com

Ελλάδα
Τηλ: +386 82880137
PV.GRC@elancoah.com

España
Tel: +34 518890402
PV.ESP@elancoah.com

France
Tél: +33 975180507
PV.FRA@elancoah.com

Hrvatska
Tel: +36 18088411
PV.HRV@elancoah.com

Ireland
Tel: +44 3308221732
PV.IRL@elancoah.com

Ísland
Sími: +45 89875379
PV.ISL@elancoah.com

Italia
Tel: +39 0282944231
PV.ITA@elancoah.com

Κύπρος

PV.LTU@elancoah.com

Luxembourg/Luxemburg
Tél/Tel: +352 20881943
PV.LUX@elancoah.com

Magyarország
Tel.: +36 18506968
PV.HUN@elancoah.com

Malta
Tel: +36 18088530
PV.MLT@elancoah.com

Nederland
Tel: +31 852084939
PV.NLD@elancoah.com

Norge
Tlf: +47 81503047
PV.NOR@elancoah.com

Österreich
Tel: +43 720116570
PV.AUT@elancoah.com

Polska
Tel.: +48 221047306
PV.POL@elancoah.com

Portugal
Tel: +351 308801355
PV.PRT@elancoah.com

România
Tel: +40 376300400
PV.ROU@elancoah.com

Slovenija
Tel: +386 82880093
PV.SVN@elancoah.com

Slovenská republika
Tel: +420 228880231
PV.SVK@elancoah.com

Suomi/Finland
Puh/Tel: +358 753252088
PV.FIN@elancoah.com

Sverige

Τηλ: +386 82880096
PV.CYP@elancoah.com

Latvija

Tel: +372 8840390
PV.LVA@elancoah.com

Tel: +46 108989397
PV.SWE@elancoah.com

United Kingdom (Northern Ireland)

Tel: +44 3308221732
PV.XXI@elancoah.com

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, D-24106 Kiel, Germany

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Veraflox 25 mg/ml oral suspension for cats

2. Composition

Each ml contains:

Active substance:

Pradofloxacin 25 mg

Excipient:

Sorbic acid (E200) 2 mg

Yellowish to beige suspension.

3. Target species

Cats.



4. Indications for use

Treatment of:

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

5. Contraindications

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

Do not use in kittens aged less than 6 weeks.

Pradofloxacin has no effects on the developing cartilage of kittens of 6 weeks of age and older.

Do not use in cats with persisting articular cartilage lesions, since 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. Special warnings

Special warnings:

Cross-resistance has been shown between pradofloxacin and other fluoroquinolones. Use of pradofloxacin should be carefully considered when susceptibility testing has shown resistance to fluoroquinolones because its effectiveness may be reduced.

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies. An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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

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

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. In case of accidental contact with the eyes, wash immediately with water. In case of contact with the skin, rinse off with water. 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 and lactation:

The safety of this veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy:

Do not use during the whole or part of pregnancy. Laboratory studies in rats have shown evidence of pradofloxacin induced eye malformations at foetotoxic and maternotoxic dosages.

Lactation:

Do not use during lactation since there are no data on pradofloxacin in kittens aged less than 6 weeks. 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.

Interaction with other medicinal products and other forms of interaction:

Concurrent administration with metal cations such as those contained in antacids or sucralfate made with magnesium hydroxide or aluminium hydroxide, or multivitamins containing iron or zinc, and dairy products containing calcium, has been reported to decrease the bioavailability of fluoroquinolones.

Therefore, the veterinary medicinal product should not be administered concurrently with antacids, sucralfate, multivitamins or dairy products, as absorption of the veterinary medicinal product may be decreased.

Further, fluoroquinolones should not be used in combination with non-steroidal anti-inflammatory drugs (NSAIDs) in animals with a history of seizures because of potential pharmacodynamic interactions in the CNS. The combination of fluoroquinolones with theophylline could increase the plasma levels of theophylline by altering its metabolism and thus should be avoided. The combined use of fluoroquinolones with digoxin should also be avoided because of potentially increased oral bioavailability of digoxin.

Overdose:

No specific antidotes for pradofloxacin (or other fluoroquinolones) are known, therefore, in case of overdose, symptomatic treatment should be given.

Intermittent vomiting was observed after repeated oral administration of 1.6 times the maximum recommended dose.

7. Adverse events

Cats:

Rare (1 to 10 animals / 10,000 animals treated):
Digestive tract disorder (e.g. Vomiting) ¹

¹ Mild and transient

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Oral use.

The recommended dose is 5 mg/kg bodyweight of pradofloxacin once daily. To ensure a correct dosage, body weight should be determined as accurately as possible. Due to the graduation of the syringe the resulting dose range is 5 to 7.5 mg/kg bodyweight according to the following table:

Bodyweight (kg)	Dose of oral suspension to be given (ml)
> 0.67 - 1	0.2
>1 – 1.5	0.3
>1.5 – 2	0.4
>2 – 2.5	0.5

>2.5 – 3	0.6
>3 – 3.5	0.7
>3.5 – 4	0.8
>4 – 5	1
>5 – 6	1.2
>6 – 7	1.4
>7 – 8	1.6
>8 – 9	1.8
>9 – 10	2

9. Advice on correct administration

Duration of treatment

The medication should be administered for as long as advised by your veterinarian. The duration of the treatment depends on the nature and severity of the infection and on the response to treatment. For most infections the following treatment courses will be sufficient:

Indication	Duration of treatment (days)
Wound infections and abscesses	7
Acute infections of the upper respiratory tract	5

The treatment should be reconsidered if no improvement of the clinical condition is observed within 3 days after starting the treatment.

Method of administration

To facilitate accurate dosing, the 15 ml bottle of Veraflox oral suspension is supplied with a 3 ml oral dosing syringe (graduation: 0.1 to 2 ml).

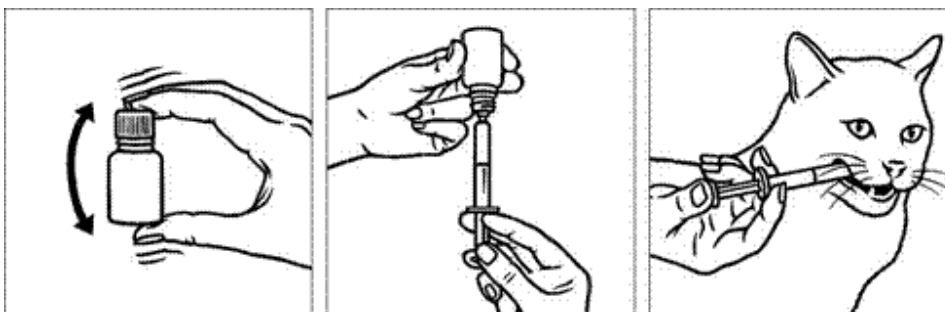
The oral suspension should be given by direct oral administration:

For monolingual packaging only:

Figures are shown below.

For multilingual packaging only:

Figures are shown at the end of the leaflet.



Shake well before use.

Draw out the equivalent dosage into the syringe.

Administer directly into the mouth.

To avoid cross-contamination, the same syringe should not be used for different animals. Thus, one syringe should only be used for one animal. After administration, the syringe should be cleaned with tap water and stored in the carton box together with the veterinary medicinal product.

Do not use the veterinary medicinal product if you notice visible signs of packaging deterioration.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original container.

Keep the bottle tightly closed.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 months

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/10/107/013-014

Pack sizes available: 15 ml bottle with a 3 ml oral dosing syringe; 30 ml bottle.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco Animal Health GmbH, Alfred-Nobel-Strasse 50, 40789 Monheim, Germany

België/Belgique/Belgien

Tél/Tel: +32 33000338

PV.BEL@elancoah.com

Република България

Тел: +48 221047815

PV.BGR@elancoah.com

Česká republika

Tel: +420 228880231

PV.CZE@elancoah.com

Danmark

Tlf: +45 78775477

PV.DNK@elancoah.com

Deutschland

Tel: +49 32221852372

PV.DEU@elancoah.com

Eesti

Tel: +372 8807513

PV.EST@elancoah.com

Ελλάδα

Τηλ: +386 82880137

PV.GRC@elancoah.com

España

Tel: +34 518890402

PV.ESP@elancoah.com

France

Tél: +33 975180507

PV.FRA@elancoah.com

Hrvatska

Tel: +36 18088411

PV.HRV@elancoah.com

Lietuva

Tel: +372 8840389

PV.LTU@elancoah.com

Luxembourg/Luxemburg

Tél/Tel: +352 20881943

PV.LUX@elancoah.com

Magyarország

Tel.: +36 18506968

PV.HUN@elancoah.com

Malta

Tel: +36 18088530

PV.MLT@elancoah.com

Nederland

Tel: +31 852084939

PV.NLD@elancoah.com

Norge

Tlf: +47 81503047

PV.NOR@elancoah.com

Österreich

Tel: +43 720116570

PV.AUT@elancoah.com

Polska

Tel.: +48 221047306

PV.POL@elancoah.com

Portugal

Tel: +351 308801355

PV.PRT@elancoah.com

România

Tel: +40 376300400

PV.ROU@elancoah.com

Ireland

Tel: +44 3308221732
PV.IRL@elancoah.com

Ísland

Sími: +45 89875379
PV.ISL@elancoah.com

Italia

Tel: +39 0282944231
PV.ITA@elancoah.com

Κύπρος

Τηλ: +386 82880096
PV.CYP@elancoah.com

Latvija

Tel: +372 8840390
PV.LVA@elancoah.com

Slovenija

Tel: +386 82880093
PV.SVN@elancoah.com

Slovenská republika

Tel: +420 228880231
PV.SVK@elancoah.com

Suomi/Finland

Puh/Tel: +358 753252088
PV.FIN@elancoah.com

Sverige

Tel: +46 108989397
PV.SWE@elancoah.com

United Kingdom (Northern Ireland)

Tel: +44 3308221732
PV.XXI@elancoah.com

Manufacturer responsible for batch release:

KVP Pharma +Veterinär Produkte GmbH, Projensdorfer Str. 324, D-24106 Kiel, Germany