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]

[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

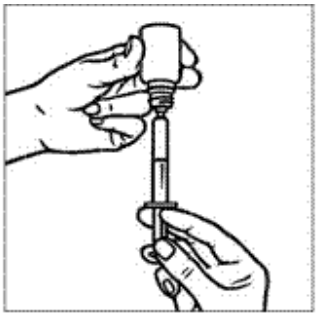
Duration of treatment
The duration of the treatment depends on the nature and severity of the infection and on the response to treatment. For most infections the following treatment courses will be sufficient:

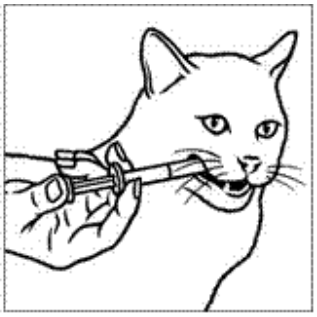
Indication	Duration of treatment (days)
Wound infections and abscesses	7
Acute infections of the upper respiratory tract	5

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).


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.

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)
Pasteurella multocida - respiratory tract infections (RTI)[1]	64	0.008	0.008	0.004-0.03
Pasteurella multocida – wound infections[2]	42	0.008	0.008	0.004 – 0.03
Escherichia coli – respiratory tract infections (RTI)[1]	22	0.015	4	0.008-8

Staphylococcus intermedius group (including *S. pseudintermedius*) – respiratory tract infections (RTI)[1]	25	0.12	2	0.008-4
Staphylococcus intermedius group (including *S. pseudintermedius*) – 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
E. coli	≤0.25	0.5-1	≥2
S. pseudintermedius	≤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.