PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

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

For 15 ml packaging only: 15 ml with 3 ml oral dosing syringe

For 30 ml packaging only: 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 logo

14. MARKETING AUTHORISATION NUMBERS

Vm 04895/5010

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

30 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 3 months.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

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 (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 at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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:

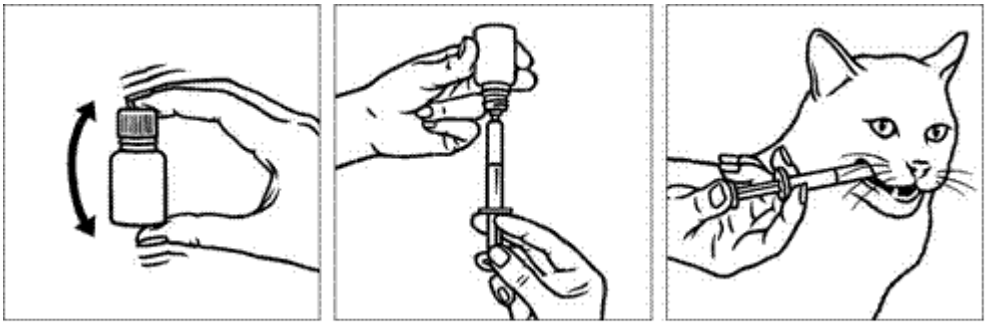
Indication	Duration of treatment (days)
Wound infections and abscesses	7
Acute infections of the upper respiratory tract	5

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.

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

Vm 04895/5010

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

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

Elanco Animal Health GmbH
Alfred-Nobel-Str. 50
40789 Monheim
Germany

PV.GBR@elancoah.com
+443308221732

Manufacturer responsible for batch release:

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

17. Other information

POM-V

Gavin Hall
Approved: 08 December 2025