PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 60 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

60 mg pradofloxacin.

3. PACKAGE SIZE

7 tablets
21 tablets
70 tablets
140 tablets

4. TARGET SPECIES

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 Animal Health GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 04895/5011

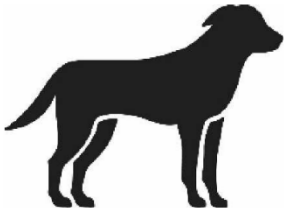
15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

60 mg pradofloxacin

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE 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 substances:

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 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 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

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 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.

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.

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

Veraflox	MA Number
15 mg tablet	Vm 04895/5009
60 mg tablet	Vm 04895/5011
120 mg tablet	Vm 04895/5008

The following pack sizes are available: 7, 21, 70 or 140 tablets.

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, 24106 Kiel, Germany.

17. Other information

POM-V

Gavin Hall

Approved: 16 June 2026