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:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

Brownish single-scored tablets with “P15” on one side
Brownish single-scored tablets with “P60” on one side
Brownish single-scored tablets with “P120” on one side
The tablet can be divided into equal doses.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats

4.2 Indications for use, specifying the target species

Dogs:

Treatment of:
- wound infections caused by susceptible strains of the *Staphylococcus intermedius* group (including *S. pseudintermedius*),
- superficial and deep pyoderma caused by susceptible strains of the *Staphylococcus intermedius* group (including *S. pseudintermedius*),
- acute urinary tract infections caused by susceptible strains of *Escherichia coli* and the *Staphylococcus intermedius* group (including *S. pseudintermedius*) and
- as adjunctive treatment to mechanical or surgical periodontal therapy in the treatment of severe infections of the gingiva and periodontal tissues caused by susceptible strains of anaerobic organisms, for example *Porphyromonas* spp. and *Prevotella* spp. (see section 4.5).

Cats:

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

4.3 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 4.7).

Cats:

Due to the lack of data, pradofloxacin should not be used in kittens aged less than 6 weeks.

Pradofloxacin has no effects on the developing cartilage of kittens of 6 weeks of age and older. However, the product must not be used in cats with persisting articular cartilage lesions, as these lesions may worsen during treatment with fluoroquinolones.

Do not use in cats with central nervous system (CNS) disorders, such as epilepsy, as fluoroquinolones could potentially cause seizures in predisposed animals.

Do not use in cats during pregnancy and lactation (see section 4.7).

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.

Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.

Use of the veterinary medicinal product deviating from instructions given in the summary of product characteristics (SPC) may increase the prevalence of bacteria resistant to the fluoroquinolones and

may decrease the effectiveness of treatment with other fluoroquinolones due to the potential for cross-resistance.

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

Due to potential harmful effects, the tablets must be kept out of the sight and reach of children.

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.

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.

4.6 Adverse reactions (frequency and seriousness)

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

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated-)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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

Pregnancy:
Do not use during pregnancy. Pradofloxacin induced eye malformations at foetal and maternal toxic doses in rats.

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.

4.8 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, Veraflox should not be administered concurrently with antacids, sucralfate, multivitamins or dairy products, as absorption of Veraflox 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.

4.9 Amounts to be administered and administration route

Oral use.

Doses

The recommended dose is 3 mg/kg bodyweight of pradofloxacin once daily. Due to the available tablet sizes the resulting dose range is 3 to 4.5 mg/kg bodyweight according to the following tables.

To ensure a correct dose, bodyweight should be determined as accurately as possible to avoid under dosing. When the dose requires a half tablet to be used the remaining portion should be given at the next administration.

Dogs:

Bodyweight of Dog (kg)	**Number of tablets**			**Pradofloxacin dose (mg/kg bw)**
	15 mg	**60 mg**	**120 mg**	
>3.4 – 5	1			3 – 4.4
5 – 7.5	1½			3 – 4.5
7.5 – 10	2			3 – 4
10 – 15	3			3 – 4.5
15 – 20		1		3 – 4
20 – 30		1½		3 – 4.5
30 – 40			1	3 – 4
40 – 60			1½	3 – 4.5
60 – 80			2	3 – 4

Cats:

Bodyweight of Cat	**Number of tablets**	**Pradofloxacin dose**

(kg)	15 mg	(mg/kg bw)
>3.4 – 5	1	3 – 4.4
5 – 7.5	1½	3 – 4.5
7.5 – 10	2	3 – 4

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)
Infections of the skin:	
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, fluoroquinolones.
ATCvet code: QJ01MA97

5.1 Pharmacodynamic properties

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 4.2) and in accordance with the prudent use recommendations in section 4.5 of this SPC.

MIC-Data

Dogs:

Bacterial species	Number of strains	MIC_{50} (µg/ml)	MIC_{90} (µg/ml)	MIC range (µg/ml)
Staphylococcus intermedius group (including *S. pseudintermedius*)	1097	0.062	0.062	0.002-4
Escherichia coli	173	0.031	0.062	0.008-16
Porphyromonas spp.	310	0.062	0.125	≤ 0.016-0.5
Prevotella spp.	320	0.062	0.25	≤ 0.016-1

The bacteria were isolated between 2001 and 2007 from clinical cases in Belgium, France, Germany, Hungary, Italy, Poland, Sweden and UK.

Cats:

Bacterial species	Number of strains	MIC_{50} (µg/ml)	MIC_{90} (µg/ml)	MIC range (µg/ml)
Pasteurella multocida	323	0.016	0.016	0.002-0.062
Escherichia coli	135	0.016	4	0.008-8
Staphylococcus intermedius group (including *S. pseudintermedius*)	184	0.062	0.125	0.016-8

The bacteria were isolated between 2001 and 2007 from clinical cases in Belgium, France, Germany, Hungary, Poland, Sweden and UK.

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Cellulose, microcrystalline
Povidone
Magnesium stearate
Silica, colloidal anhydrous
Artificial beef flavour
Croscarmellose sodium

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

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

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Folding cartons containing aluminium blister packs. One blister contains 7 tablets.

The following pack sizes are available:

- 7 tablets
- 21 tablets
- 70 tablets
- 140 tablets

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Bayer Animal Health GmbH
D-51368 Leverkusen
Germany

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/107/001-012

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12/04/2011
Date of last renewal: 07/01/2016

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

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:

Preservative: Sorbic acid (E200) 2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

Yellowish to beige suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

Treatment of:

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

4.3 Contraindications

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

Due to the lack of data, pradofloxacin should not be used in kittens aged less than 6 weeks.

Pradofloxacin has no effects on the developing cartilage of kittens of 6 weeks of age and older. However the product should not be used in cats with persisting articular cartilage lesions, as these lesions may worsen during treatment with fluoroquinolones.

Do not use in cats with central nervous system (CNS) disorders, such as epilepsy, as fluoroquinolones could potentially cause seizures in predisposed animals.

Do not use in cats during pregnancy and lactation (see section 4.7).

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.

Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.

Use of the veterinary medicinal product deviating from instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other fluoroquinolones due to the potential for cross-resistance.

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

Due to potential harmful effects, the bottles and the filled syringes must be kept out of the sight and reach of children.

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.

4.6 Adverse reactions (frequency and seriousness)

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

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated-)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 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 pregnancy. Pradofloxacin induced eye malformations at foetal and maternal toxic dosages in rats.

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.

4.8 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, Veraflox should not be administered concurrently with antacids, sucralfate, multivitamins or dairy products, as absorption of Veraflox 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.

4.9 Amounts to be administered and administration route

Oral use.

Doses

The recommended dose is 5 mg/kg bodyweight of pradofloxacin once daily. 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 of Cat (kg)	**Dose of Oral suspension to be given (ml)**	**Pradofloxacin dose (mg/kg bw)**
> 0.67 - 1	0.2	5 – 7.5
1 – 1.5	0.3	5 – 7.5
1.5 – 2	0.4	5 – 6.7
2 – 2.5	0.5	5 – 6.3
2.5 – 3	0.6	5 – 6
3 – 3.5	0.7	5 – 5.8
3.5 – 4	0.8	5 – 5.7
4 – 5	1	5 – 6.3
5 – 6	1.2	5 – 6
6 – 7	1.4	5 – 5.8
7 – 8	1.6	5 – 5.7
8 – 9	1.8	5 – 5.6

9 – 10	2	5 – 5.6

To ensure a correct dose, bodyweight should be determined as accurately as possible to avoid under dosing.

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

Duration of treatment

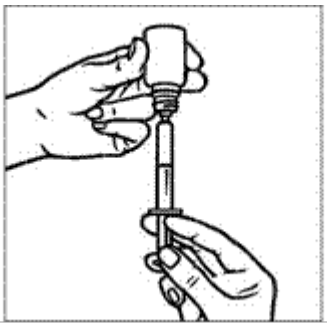
The duration of the treatment depends on the nature and severity of the infection and on the response to treatment. For most infections the following treatment courses will be sufficient:

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

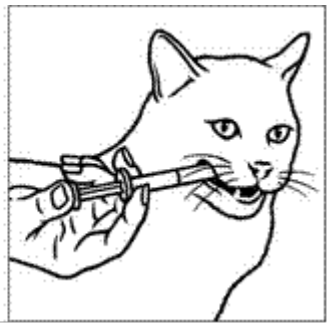
The treatment should be reconsidered if no improvement of the clinical condition is observed within 3 days after starting the treatment.

Method of administration

Shake well before use.



Draw out the equivalent dosage into the syringe.



Administer directly into the mouth.

In order 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, fluoroquinolones.
ATCvet code: QJ01MA97

5.1 Pharmacodynamic properties

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 4.2) and in accordance with the prudent use recommendations in section 4.5 of this SPC.

MIC-Data

Bacterial species	Number of strains	MIC_{50} (µg/ml)	MIC_{90} (µg/ml)	MIC range (µg/ml)
Pasteurella multocida	323	0.016	0.016	0.002-0.062
Escherichia coli	135	0.016	4	0.008-8
Staphylococcus intermedius group (including *S. pseudintermedius*)	184	0.062	0.125	0.016-8

The bacteria were isolated between 2001 and 2007 from clinical cases in Belgium, France, Germany, Hungary, Poland, Sweden and UK.

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Amberlite IRP 64
Sorbic acid
Ascorbic acid
Xanthan gum
Propylene glycol
Vanilla flavour
Purified water

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the bottle: 3 months

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Veraflox oral suspension is supplied in two different presentations:

Folding carton containing 15 ml white high density polyethylene (HDPE) bottle with a polyethylene adapter and a child-resistant closure and a 3 ml polypropylene oral dosing syringe (graduation: 0.1 to 2 ml).

Folding carton containing 30 ml white high density polyethylene (HDPE) bottle with a polyethylene adapter and a child-resistant closure.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Bayer Animal Health GmbH
D-51368 Leverkusen
Germany

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/107/013-014

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12/04/2011
Date of last renewal: 07/01/2016

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Strasse 324
D-24106 Kiel
Germany

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Folding carton containing 1 blister strip (1 x 7 tablets of 15 mg)
Folding carton containing 3 blister strips (3 x 7 tablets of 15 mg)
Folding carton containing 10 blister strips (10 x 7 tablets of 15 mg)
Folding carton containing 20 blister strips (20 x 7 tablets of 15 mg)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 15 mg tablets for dogs and cats
pradofloxacin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 15 mg pradofloxacin.

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

7 tablets
21 tablets
70 tablets
140 tablets

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bayer Animal Health GmbH
D-51368 Leverkusen
Germany

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/107/001 7 tablets
EU/2/10/107/002 21 tablets
EU/2/10/107/003 70 tablets
EU/2/10/107/004 140 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Folding carton containing 1 blister strip (1 x 7 tablets of 60 mg)
Folding carton containing 3 blister strips (3 x 7 tablets of 60 mg)
Folding carton containing 10 blister strips (10 x 7 tablets of 60 mg)
Folding carton containing 20 blister strips (20 x 7 tablets of 60 mg)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 60 mg tablets for dogs
pradofloxacin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 60 mg pradofloxacin.

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

7 tablets
21 tablets
70 tablets
140 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bayer Animal Health GmbH
D-51368 Leverkusen
Germany

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/107/005 7 tablets
EU/2/10/107/006 21 tablets
EU/2/10/107/007 70 tablets
EU/2/10/107/008 140 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Folding carton containing 1 blister strip (1 x 7 tablets of 120 mg)
Folding carton containing 3 blister strips (3 x 7 tablets of 120 mg)
Folding carton containing 10 blister strips (10 x 7 tablets of 120 mg)
Folding carton containing 20 blister strips (20 x 7 tablets of 120 mg)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 120 mg tablets for dogs
pradofloxacin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 120 mg pradofloxacin.

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

7 tablets
21 tablets
70 tablets
140 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bayer Animal Health GmbH
D-51368 Leverkusen
Germany

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/107/009 7 tablets
EU/2/10/107/010 21 tablets
EU/2/10/107/011 70 tablets
EU/2/10/107/012 140 tablets

17. MANUFACTURER'S BATCH NUMBER

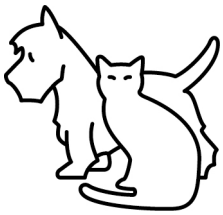
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Aluminium blister of 7 tablets (15 mg)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 15 mg tablets
pradofloxacin



2. NAME OF THE MARKETING AUTHORISATION HOLDER

Bayer

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

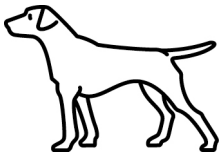
For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Aluminium blister of 7 tablets (60 mg)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 60 mg tablets
pradofloxacin



2. NAME OF THE MARKETING AUTHORISATION HOLDER

Bayer

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot{number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

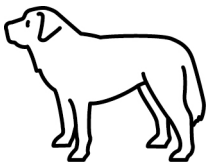
For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Aluminium blister of 7 tablets (120 mg)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 120 mg tablets
pradofloxacin



2. NAME OF THE MARKETING AUTHORISATION HOLDER

Bayer

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Folding carton containing a HDPE bottle (15 ml oral suspension)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 25 mg/ml oral suspension for cats
pradofloxacin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Pradofloxacin 25 mg/ml
Preservative: Sorbic acid (E200)

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

- 15 ml bottle and a 3ml oral dosing syringe

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Avoid introduction of contamination during use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 3 months

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS , IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bayer Animal Health GmbH
D-51368 Leverkusen
Germany

16. MARKETING AUTHORISATION NUMBER

EU/2/10/107/013

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle label (15 ml oral suspension)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 25 mg/ml oral suspension for cats
pradofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Pradofloxacin 25 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

15 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use.
Shake well before use.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP {month/year}
Once opened, use by _____

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Folding carton containing a HDPE bottle (30 ml oral suspension)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 25 mg/ml oral suspension for cats
pradofloxacin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Pradofloxacin 25 mg/ml
Preservative: Sorbic acid (E200)

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

30 ml bottle

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Avoid introduction of contamination during use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 3 months.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS , IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only – To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bayer Animal Health GmbH
D-51368 Leverkusen
Germany

16. MARKETING AUTHORISATION NUMBER

EU/2/10/107/014

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle label (30 ml oral suspension)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 25 mg/ml oral suspension for cats
pradofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Pradofloxacin 25 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

30 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use.
Shake well before use.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP {month/year}
Once opened, use by _____

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Veraflox 15 mg tablets for dogs and cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder :
Bayer Animal Health GmbH
D-51368 Leverkusen
Germany

Manufacturer responsible for batch release:
KVP Pharma +Veterinär Produkte GmbH
Projensdorfer Str. 324
D-24106 Kiel
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 15 mg tablets for dogs and cats
pradofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each tablet contains:

Active substance:
Pradofloxacin 15 mg

Brownish single-scored tablets with “P15” on one side
The tablet can be divided into equal doses.

4. INDICATIONS

Dogs:

Treatment of:
- wound infections caused by susceptible strains of the *Staphylococcus intermedius* group (including *S. pseudintermedius*),
- superficial and deep pyoderma caused by susceptible strains of the *Staphylococcus intermedius* group (including *S. pseudintermedius*),
- acute urinary tract infections caused by susceptible strains of *Escherichia coli* and the *Staphylococcus intermedius* group (including *S. pseudintermedius*) and
- as adjunctive treatment to mechanical or surgical periodontal therapy in the treatment of severe infections of the gingiva and periodontal tissues caused by susceptible strains of anaerobic organisms, for example *Porphyromonas* spp. and *Prevotella* spp. (see section “Special Warnings”).

Cats:

Treatment of:

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

5. CONTRAINDICATIONS

-
Do not use in cases of hypersensitivity to the active substances 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:

Due to the lack of data, pradofloxacin should not be used in kittens aged less than 6 weeks.

Pradofloxacin has no effects on the developing cartilage of kittens of 6 weeks of age and older. However the product should not be used in cats with persisting articular cartilage lesions, as these lesions may worsen during treatment with fluoroquinolones.

Do not use in cats with central nervous system (CNS) disorders, such as epilepsy, as fluoroquinolones could potentially cause seizures in predisposed animals.

Do not use in cats during pregnancy and lactation (see section “Special Warnings”).

6. ADVERSE REACTIONS

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

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated-)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs, cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use.

Doses

The recommended dose is 3 mg/kg bodyweight of pradofloxacin once daily according to the following tables. To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. When the dose requires a half tablet to be used the remaining portion should be given at the next administration.

Dogs:

Bodyweight of Dog (kg)	Number of 15 mg tablets	Pradofloxacin dose (mg/kg bw)
>3.4 – 5	1	3 – 4.4
5 – 7.5	1½	3 – 4.5
7.5 – 10	2	3 – 4.
10 – 15	3	3 – 4.5
For dogs over 15 kg, use 60 mg or 120 mg pradofloxacin tablets.		

Cats:

Bodyweight of Cat (kg)	Number of 15 mg tablets	Pradofloxacin dose (mg/kg bw)
>3.4 – 5	1	3 – 4.4
5 – 7.5	1½	3 – 4.5
7.5 – 10	2	3 – 4

Duration of treatment

The medication should be administered for as long as advised by your veterinarian. The duration of treatment depends on the severity of the infection and how well the medicine works in your pet. For most infections the following durations of treatment are recommended:

Dogs:

Indication	Duration of treatment (days)
Infections of the skin:	
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

Ask your veterinarian for advice if no improvement of the clinical conditions is observed within 3 days after starting the treatment, although for superficial pyoderma this time should be increased to 7 days, and for deep pyoderma to 14 days.

Cats:

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

Ask your veterinarian for advice if no improvement of the clinical condition is observed within 3 days after starting the treatment.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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 label.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Whenever possible, Veraflox should only be used based on susceptibility testing.

Official and local antimicrobial policies should be taken into account when the product is used.

Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.

Use of the product deviating from instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other fluoroquinolones due to the potential for cross-resistance.

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

Veraflox 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, Veraflox 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.

Tell your veterinarian if your animal has impaired kidney function. Excretion via kidneys is an important elimination route for pradofloxacin in dogs and, therefore, pradofloxacin should be used with caution in animals with impaired kidney function.

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

Due to potential harmful effects, the tablets must be kept out of the sight and reach of children.

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.

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, lactation and Fertility:
The safety of Veraflox has not been established during pregnancy and lactation in cats and dogs.

Pregnancy:
Do not use during pregnancy. Pradofloxacin induced eye malformations at foetal and maternal toxic dosages in rats.

Lactation:
Do not use during lactation. Laboratory studies in puppies have shown evidence of arthropathy (damage to the cartilage of joints) 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.

Interactions with other medicinal products and other forms of interaction:
There are some medicines that you should not give to your animal during treatment because if given together they might cause serious adverse effects. Tell your veterinarian about all medicines that you intend to give the animal.

Veraflox should not be administered concurrently with antacids or sucralfate (used for gastric acidity), multivitamins or dairy products, as the absorption of Veraflox may be decreased. Further, Veraflox should not be used in combination with non-steroidal anti-inflammatory drugs (NSAIDs; used with pain, fever or inflammation) in animals with a history of seizures because of potential higher sensitivity to seizure formation. The combined use of Veraflox with theophylline (used with chronic respiratory conditions) or digoxin (used with congestive heart failure) should also be avoided because of potentially higher blood levels which could increase the effects of these drugs.

Overdose (symptoms, emergency procedures, antidotes):

Vomiting and soft faeces may be symptoms of overdose. No specific antidotes for pradofloxacin (or other fluoroquinolones) are known; therefore, in case of overdose symptomatic treatment should be given.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater or household waste.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

The following pack sizes are available:

- 7 tablets
- 21 tablets
- 70 tablets
- 140 tablets

Not all pack sizes may be marketed.

PACKAGE LEAFLET:
Veraflox 60 mg and 120 mg tablets for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder :
Bayer Animal Health GmbH
D-51368 Leverkusen
Germany

Manufacturer responsible for batch release:
KVP Pharma +Veterinär Produkte GmbH
Projensdorfer Str. 324
D-24106 Kiel
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 60 mg tablets for dogs
Veraflox 120 mg tablets for dogs
pradofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each tablet contains:

Active substance:

Pradofloxacin	60 mg
Pradofloxacin	120 mg

Brownish single-scored tablets with “P60” on one side
Brownish single-scored tablets with “P120” on one side
The tablet can be divided into equal doses.

4. INDICATIONS

Dogs:

Treatment of:
- wound infections caused by susceptible strains of the *Staphylococcus intermedius* group (including *S. pseudintermedius*),
- superficial and deep pyoderma caused by susceptible strains of the *Staphylococcus intermedius* group (including *S. pseudintermedius*),
- acute urinary tract infections caused by susceptible strains of *Escherichia coli* and the *Staphylococcus intermedius* group (including *S. pseudintermedius*) and
- as adjunctive treatment to mechanical or surgical periodontal therapy in the treatment of severe infections of the gingiva and periodontal tissues caused by susceptible strains of anaerobic

organisms, for example *Porphyromonas* spp. and *Prevotella* spp. (see section "Special Warnings").

5. CONTRAINDICATIONS

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

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").

6. ADVERSE REACTIONS

Mild transient gastro-intestinal disturbances including vomiting have been observed in rare cases

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals teated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated-)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use.

Doses

The recommended dose is 3 mg/kg bodyweight of pradofloxacin once daily according to the following tables. To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. When the dose requires a half tablet to be used the remaining portion should be given at the next administration.

Dogs:

Bodyweight of Dog (kg)	Number of tablets		Pradofloxacin dose (mg/kg bw)
	60 mg	120 mg	
For dogs under 15 kg, use 15 mg pradofloxacin tablets.			
15 – 20	1		3 – 4
20 – 30	1½		3 – 4.5
30 – 40		1	3 – 4
40 – 60		1½	3 – 4.5
60 – 80		2	3 – 4

Duration of treatment

The medication should be administered for as long as advised by your veterinarian. The duration of treatment depends on the severity of the infection and how well the medicine works in your pet. For most infections the following durations of treatment are recommended:

Indication	Duration of treatment (days)
Infections of the skin:	
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

Ask your veterinarian for advice if no improvement of the clinical conditions is observed within 3 days after starting the treatment, although for superficial pyoderma this time should be increased to 7 days, and for deep pyoderma to 14 days.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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 label.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Whenever possible, Veraflox should only be used based on susceptibility testing.

Official and local antimicrobial policies should be taken into account when the product is used.

Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.

Use of the product deviating from instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other fluoroquinolones due to the potential for cross-resistance.

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

Veraflox 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, Veraflox 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.

Tell your veterinarian if your animal has impaired kidney function. Excretion via kidneys is an important elimination route for pradofloxacin in dogs and, therefore, pradofloxacin should be used with caution in animals with impaired kidney function.

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

Due to potential harmful effects, the tablets must be kept out of the sight and reach of children.

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.

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, lactation and Fertility:
The safety of Veraflox has not been established during pregnancy and lactation in dogs.

Pregnancy:
Do not use during pregnancy. Pradofloxacin induced eye malformations at foetal and maternal toxic dosages in rats.

Lactation:
Do not use during lactation. Laboratory studies in puppies have shown evidence of arthropathy (damage to the cartilage of joints) 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.

Interactions with other medicinal products and other forms of interaction:
There are some medicines that you should not give to your animal during treatment because if given together they might cause serious adverse effects. Tell your veterinarian about all medicines that you intend to give the animal.

Veraflox should not be administered concurrently with antacids or sucralfate (used for gastric acidity), multivitamins or dairy products, as the absorption of Veraflox may be decreased. Further, Veraflox should not be used in combination with non-steroidal anti-inflammatory drugs (NSAIDs; used with pain, fever or inflammation) in animals with a history of seizures because of potential higher sensitivity to seizure formation. The combined use of Veraflox with theophylline (used with chronic respiratory conditions) or digoxin (used with congestive heart failure) should also be avoided because of potentially higher blood levels which could increase the effects of these drugs.

Overdose (symptoms, emergency procedures, antidotes):
Vomiting and soft faeces may be symptoms of overdose. No specific antidotes for pradofloxacin (or other fluoroquinolones) are known; therefore, in case of overdose symptomatic treatment should be given.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater or household waste.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

The following pack sizes are available:

- 7 tablets
- 21 tablets
- 70 tablets
- 140 tablets

Not all pack sizes may be marketed.

PACKAGE LEAFLET:
Veraflox 25 mg/ml oral suspension for cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder :
Bayer Animal Health GmbH
D-51368 Leverkusen
Germany

Manufacturer responsible for batch release:
KVP Pharma +Veterinär Produkte GmbH
Projensdorfer Str. 324
D-24106 Kiel
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veraflox 25 mg/ml oral suspension for cats
pradofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Oral suspension containing 25 mg/ml pradofloxacin

Preservative: Sorbic acid (E200) 2 mg/ml

Yellowish to beige suspension.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

Due to the lack of data, pradofloxacin should not be used in kittens aged less than 6 weeks.

Pradofloxacin has no effects on the developing cartilage of kittens of 6 weeks of age and older. However the product should not be used in cats with persisting articular cartilage lesions, as these lesions may worsen during treatment with fluoroquinolones.

Do not use in cats with central nervous system (CNS) disorders, such as epilepsy, as fluoroquinolones could potentially cause seizures in predisposed animals.

Do not use in cats during pregnancy and lactation (see section "Special Warnings").

6. ADVERSE REACTIONS

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

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated-)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use.

Dosages
The recommended dose is 5- mg/kg bodyweight of pradofloxacin once daily. 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 of Cat (kg)	**Dose of oral suspension to be given (ml)**	**Pradofloxacin dose (mg/kg bw)**
> 0.67 - 1	0.2	5 – 7.5
1 – 1.5	0.3	5 – 7.5
1.5 – 2	0.4	5 – 6.7
2 – 2.5	0.5	5 – 6.3
2.5 – 3	0.6	5 – 6
3 – 3.5	0.7	5 – 5.8
3.5 – 4	0.8	5 – 5.7
4 – 5	1	5 – 6.3
5 – 6	1.2	5 – 6
6 – 7	1.4	5 – 5.8
7 – 8	1.6	5 – 5.7
8 – 9	1.8	5 – 5.6
9 – 10	2	5 – 5.6

Duration of treatment

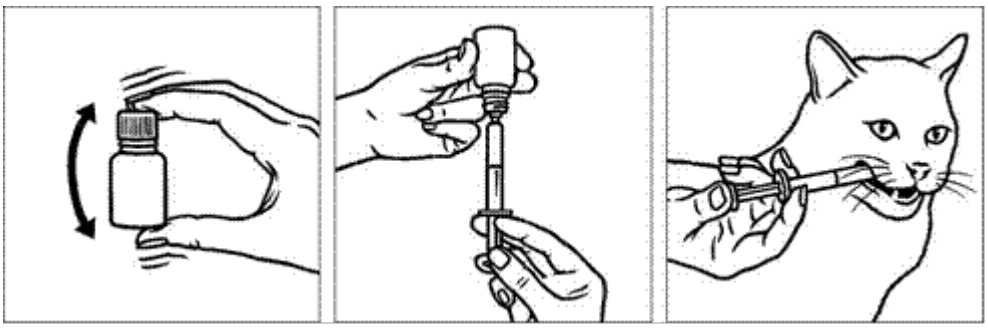
The medication should be administered for as long as advised by your veterinarian. The duration of treatment depends on the severity of the infection and how well the medicine works in your pet. For most infections the following durations of treatment are recommended:

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

Ask your veterinarian for advice if no improvement of the clinical condition is observed within 3 days after starting the treatment.

9. ADVICE ON CORRECT ADMINISTRATION

The oral suspension should be given by direct oral administration as shown below:



Shake well before use. | Draw out the equivalent dosage into the syringe. | Administer directly into the mouth.

In order to avoid cross-contamination, the same syringe should not be used for different animals. One syringe should therefore only be used for one animal. After administration the syringe should be cleaned with tap water and stored with the bottle in the carton box.

10. WITHDRAWAL PERIOD(S)

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 label.
Shelf life after first opening the container: 3 months.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Whenever possible, Veraflox should only be used based on susceptibility testing.

Official and local antimicrobial policies should be taken into account when the product is used.

Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.

Use of the product deviating from instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other fluoroquinolones due to the potential for cross-resistance.

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:

Due to potential harmful effects, the bottle and the filled syringes must be kept out of the sight and reach of children.

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, lactation, Fertility:
The safety of Veraflox has not been established in queens during pregnancy and lactation.

Pregnancy:
Do not use during pregnancy. Pradofloxacin induced eye malformations at foetal and maternal toxic dosages in rats.

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.

Interactions with other medicinal products and other forms of interaction:
There are some medicines that you should not give to your animal during treatment because if given together they might cause serious adverse effects. Tell your veterinarian about all medicines that you intend to give the animal.

Veraflox should not be administered concurrently with antacids or sucralfate (used for gastric acidity), multivitamins or dairy products, as the absorption of Veraflox may be decreased. Further, Veraflox should not be used in combination with non-steroidal anti-inflammatory drugs (NSAIDs;

used with pain, fever or inflammation) in animals with a history of seizures because of potential higher sensitivity to seizure formation. The combined use of Veraflox with theophylline (used with chronic respiratory conditions) or digoxin (used with congestive heart failure) should also be avoided because of potentially higher blood levels which could increase the effects of these drugs.

Overdose (symptoms, emergency procedures, antidotes):
Vomiting may be a symptom of overdose. No specific antidotes for pradofloxacin (or other fluoroquinolones) are known; therefore, in case of overdose symptomatic treatment should be given.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater or household waste.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Veraflox oral suspension is supplied in two different presentations:

- 15 ml bottle and a 3ml oral dosing syringe
- 30 ml bottle

Not all pack sizes may be marketed.