

148 mm

75 mm

Pharmaco-
code
Read Direction

DUMINY

Duration of treatment

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

Dogs:

Indication	Duration of treatment (days)
Skin infections:	
Superficial pyoderma	14 – 21
Deep pyoderma	14 – 35
Wound infections	7
Acute infections of the urinary tract	7 – 21
Severe infections of the gingiva and periodontal tissues	7

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

Cats:

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

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

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 USE DURING PREGNANCY, LACTATION OR LAY).

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 be 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 USE DURING PREGNANCY, LACTATION OR LAY).

WARNINGS AND PRECAUTIONS

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.

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.

USE DURING PREGNANCY, LACTATION OR LAY

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

Pregnancy:

Do not use during the whole or part of 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.

ADVERSE REACTIONS

Dogs and cats:

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

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.

WITHDRAWAL PERIOD

Not applicable.

STORAGE CONDITIONS

Do not store above 25°C.
Shelf life of the veterinary medicinal product as packaged for sale: 3 years

DOSAGE FORMS AND PACKAGING AVAILABLE

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

The following pack sizes are available:

- 7 tablets

- 70 tablets

Not all pack sizes may be marketed.

MANUFACTURED BY

Argenta US Manufacturing LLC
12707 Shawnee Mission Parkway,
Shawnee, Kansas 66216, United States.

MARKETING AUTHORISATION HOLDER

Elanco Malaysia Sdn Bhd
Unit 5.04, Level 5 & 6, Tower Block, The Bousteador,
No. 10, Jalan PJU 7/6, Mutiara Damansara,
47800 Petaling Jaya, Selangor, Malaysia.

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