Elanco™
Pradalex™
(pradofloxacin injection)

200 mg pradofloxacin/mL injectable solution
Antimicrobial

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Federal law prohibits the extra-label use of this drug in food-producing animals.

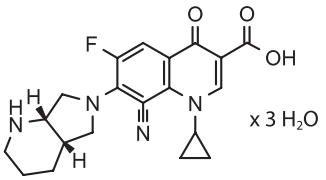
To ensure responsible antimicrobial drug use, use of pradofloxacin should be limited to treatment of bovine respiratory disease (BRD) in cattle and treatment of swine respiratory disease (SRD) in swine only after consideration of other non-fluoroquinolone therapeutic options.

PRODUCT DESCRIPTION

Pradalex (pradofloxacin injection) is a sterile, ready-to-use injectable antimicrobial solution that contains pradofloxacin, a broad-spectrum fluoroquinolone antimicrobial agent.

Each mL of Pradalex contains 227 mg pradofloxacin trihydrate; equivalent to 200 mg of pradofloxacin. Excipients are citric acid (antioxidant) 1 mg, gluconolactone (for pH adjustment) 77 mg, and water for injection q.s.

Pradofloxacin is a fluoroquinolone antimicrobial and belongs to the class of quinoline carboxylic acid derivatives. Its chemical name is 8-cyano-1-cyclopropyl-6-fluoro-7-[(4aS,7aS)-octahydro-6Hpyrrolo[3,4-b]pyridin-6-yl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid.



Pradofloxacin Trihydrate

INDICATIONS

Cattle: Pradalex is indicated for the treatment of BRD associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni* and *Mycoplasma bovis* in cattle intended for slaughter (beef calves 2 months of age and older, growing beef steers, growing beef heifers, and beef bulls intended for slaughter), and in cattle intended for breeding less than 1 year of age (replacement beef and dairy heifers less than 1 year of age and beef and dairy bulls less than 1 year of age). Not for use in cattle intended for breeding 1 year of age and older (replacement beef and dairy heifers 1 year of age and older, beef and dairy bulls 1 year of age and older, and beef and dairy cows), beef calves less than 2 months of age, dairy calves, and veal calves.

Swine: Pradalex is indicated for the treatment of SRD associated with *Bordetella bronchiseptica, Glaesserella (Haemophilus) parasuis, Pasteurella multocida, Streptococcus suis*, and *Mycoplasma hyopneumoniae* in weaned swine intended for slaughter (nursery, growing, and finishing swine, boars intended for slaughter, barrows, gilts intended for slaughter, and sows intended for slaughter).

Not for use in swine intended for breeding (boars intended for breeding, replacement gilts, and sows intended for breeding) and in nursing piglets.

DOSAGE AND ADMINISTRATION

Cattle: Administer once as a subcutaneous injection at a dosage of 10 mg/kg (2.3 mL/100 lb) body weight. Do not inject more than 15 mL per subcutaneous injection site.

Table 1. Pradalex Dose Guide for Cattle (2.3 mL/100 lbs)

Weight (lb)	Dose Volume (mL)
100	2.3
200	4.6
300	6.9
400	9.2
500	11.5
600	13.8
700	16.1
800	18.4
900	20.7

Swine: Administer once as an intramuscular injection in the neck at a dosage of 7.5 mg/kg (1.7 mL/100 lb) body weight. Do not inject more than 5 mL per intramuscular injection site.

Table 2. Pradalex Dose Guide for Swine (1.7 mL/100 lbs)

Weight (lb)	Dose Volume (mL)
15	0.3
30	0.5
50	0.9
100	1.7
150	2.6
200	3.4
250	4.3

Dilution of Pradalex: Pradalex may be diluted with sterile water, sterile saline (0.9%), or 5% dextrose (D5W) prior to injection. The diluted product should be used within 24 hours. Store diluted solution in amber glass bottles between 25-40°C (77-104°F).

Table 3. Dilution Guide for Swine*

Swine Weight	mL of Pradalex	mL of diluent**	Number of doses
5 lb	8.5 mL	91.5 mL	100
10 lb	17 mL	83 mL	100
15 lb	25.6 mL	74.4 mL	100
20 lb	34.1 mL	65.9 mL	100
25 lb	42.6 mL	57.4 mL	100
30 lb	51.1 mL	48.9 mL	100
35 lb	59.7 mL	40.3 mL	100
40 lb	68.2 mL	31.8 mL	100
45 lb	76.7 mL	23.3 mL	100
50 lb	85.2 mL	14.8 mL	100

*For 1 mL dose volume from diluted solution
**Pradalex can be diluted with sterile water, sterile saline (0.9%), or 5% dextrose (D5W) for injection

Use bottle within 6 months of first puncture. When administering from the 250 mL bottle, puncture a maximum of 120 times. If more than 120 punctures are anticipated, the use of multi-dosing equipment is recommended. When using a draw-off spike or needle with bore diameter larger than 16-gauge, discard any product remaining in the vial immediately after use.

WITHDRAWAL PERIODS and RESIDUE WARNINGS

Cattle intended for human consumption must not be slaughtered within 4 days of treatment. Swine intended for human consumption must not be slaughtered within 2 days of treatment. Not for use in female dairy cattle 1 year of age and older, including dry dairy cows; use in these cattle may cause drug residues in milk and/or in calves born to these cows. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves; a withdrawal period has not been established for this product in pre-ruminating calves.

USER SAFETY WARNINGS

Not for use in humans. Keep out of reach of children. Avoid contact with eyes and skin. In case of ocular contact, immediately remove contact lenses and flush eyes with copious amounts of water for 15 minutes. In case of dermal contact, wash skin with soap and water for at least 20 seconds. Consult a physician if irritation persists following ocular or dermal exposures, or in case of accidental ingestion. Individuals with a history of hypersensitivity to quinolones should avoid this product. In humans, there is a risk of user photosensitization within a few hours after excessive exposure to quinolones. If excessive accidental exposure occurs, avoid direct sunlight. Do not eat, drink or smoke while handling this product. To obtain a copy of the Safety Data Sheet, contact Elanco at 1-800-428-4441.

ANIMAL SAFETY WARNINGS

Not for use in animals intended for breeding because the effects of Pradalex on bovine and swine reproductive performance, pregnancy, and lactation have not been determined. Not for use in pre-ruminating calves or nursing piglets because safety and effectiveness has not been demonstrated. Swelling and inflammation may be seen at the injection site after administration. These local tissue reactions may persist beyond the slaughter withdrawal period and may result in trim loss of edible tissue at slaughter.

Quinolones should be used with caution in animals with known or suspected central nervous system (CNS) disorders. In such animals, quinolones have, in rare instances, been associated with CNS stimulation that may lead to convulsive seizures. Quinolones have been shown to produce erosions of cartilage of weight-bearing joints and other signs of arthropathy in immature animals of various species. See Target Animal Safety section for additional information.

ADVERSE REACTIONS

Mild to moderate inflammatory changes of the injection site may be seen in cattle and swine treated with Pradalex.

CONTACT INFORMATION

To report suspected adverse drug experiences, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Elanco at 1-800-428-4441. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

CLINICAL PHARMACOLOGY

Mechanism of Action

Pradofloxacin is a synthetic fluoroquinolone antibacterial drug. Pradofloxacin acts via inhibition of DNA gyrase and topoisomerase IV enzymes in bacteria to inhibit DNA and RNA synthesis. It is bactericidal with a broad spectrum of activity. As a class, fluoroquinolones are considered concentration dependent antimicrobials. Pradofloxacin induces long post-antibiotic effects (PAE) and extended post-antibiotic sub-MIC effects (PA SME), both in aerobic and anaerobic bacteria.

Pharmacokinetics

Cattle: The pharmacokinetic parameters of pradofloxacin in Table 4 were determined from two studies following subcutaneous administration of pradofloxacin in 4- to-5-month-old weaned calves weighing 158 to 319 kg.

Pradofloxacin exposure (Cmax and AUC) was dose proportional over a 10 to 50 mg/kg dose range with no accumulation when administered once every 4 days over 8 days.

Pradofloxacin was excreted in both the urine and the feces, largely unchanged, with the majority of the administered dose being excreted in the first 24 hours post-dosing.

Swine: The pharmacokinetic parameters of pradofloxacin in Table 4 were determined following intramuscular administration of pradofloxacin in 18-day-old weaned pigs weighing 5.5 to 7.9 kg. Pradofloxacin exposure (C_{max} and AUC) was dose proportional over a 7.5 to 37.5 mg/kg dose range with no accumulation when administered once every 2 days over 4 days.

Pradofloxacin was excreted in both the urine and the feces, largely unchanged, with approximately one-third of the administered dose being excreted in the first 24 hours post-dosing.

Table 4. Arithmetic mean (± standard deviation) plasma pradofloxacin pharmacokinetic parameters following the first of three administrations of Pradalex (pradofloxacin injection).

Pharmacokinetic Parameter	Weaned calves (N=12) 10 mg/kg BW SC	Weaned pigs (N = 8) 7.5 mg/kg BW IM
C_{max} (µg/mL)	1.9 ± 0.4	2.5 ± 1.9
T_{max} (hours)[a]	1 (1 to 2)	0.75 (0.5 to 2)
AUC_{last} (hr*µg/mL)	10.5 ± 1.2	26.2 ± 3.7
$t_{1/2}$ (hours)	2.8 ± 0.4[b]	8.5 ± 2.6

[a] Reported as: Median (range)
[b] N=11 due to inability to calculate half-life in 1 animal
C_{max} = maximum concentration
T_{max} = time to maximum concentration
AUC_{last} = area under the curve from the time of dosing to the time of the last measurable concentration
$t_{½}$ = half-life

MICROBIOLOGY

Cattle: The minimal inhibitory concentrations (MICs) of pradofloxacin were determined for isolates of *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* which were obtained from cattle enrolled in the 2015 BRD field study conducted in the U.S. MIC determinations were completed using Clinical and Laboratory Standards Institute (CLSI) standard methods except for *M. bovis*. The methods and quality control performance standards for *M. bovis* were validated with a multi-center laboratory study. The results are shown below in Table 5.

Table 5. Pradofloxacin MIC values* of BRD pathogens isolated from the 2015 field study.

BRD Pathogens	No. of Isolates	MIC50** (µg/mL)	MIC90** (µg/mL)	MIC range (µg/mL)
M. haemolytica	365	0.008	2	0.001 to 2
P. multocida	248	0.008	0.015	0.001 to 0.12
H. somni	106	0.015	0.015	0.015 to 0.25
M. bovis	159	0.12	0.5	0.002 to 1

* The correlation between *in vitro* susceptibility data and clinical effectiveness is unknown.
** The lowest MIC to encompass 50% and 90% of the most susceptible isolates, respectively.

Swine: The MICs of pradofloxacin were determined for isolates of *Bordetella bronchiseptica, Glaesserella (Haemophilus) parasuis, Pasteurella multocida* and *Streptococcus suis* which were obtained from swine enrolled in the 2017 SRD field study conducted in the U.S. MIC determinations were completed using CLSI standard methods except for *G. parasuis*. The methods for *G. parasuis* were validated with a multi-center laboratory study. The results are shown below in Table 6.

Table 6. Pradofloxacin MIC values* of SRD pathogens isolated from the 2017 field study.

SRD Pathogens	No. of Isolates	MIC50** (µg/mL)	MIC90** (µg/mL)	MIC range (µg/mL)
B. bronchiseptica	111	0.12	0.12	0.12 to 0.25
G. parasuis	93	0.001	0.004	0.00025 to 0.008
P. multocida	99	0.004	0.008	0.004 to 0.008
S. suis	212	0.06	0.25	0.015 to 4

* The correlation between *in vitro* susceptibility data and clinical effectiveness is unknown.
** The lowest MIC to encompass 50% and 90% of the most susceptible isolates, respectively.

EFFECTIVENESS

Cattle: The effectiveness of Pradalex for the treatment of BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* was demonstrated in a multi-site natural infection field study conducted in the U.S. A total of 630 commercial, mixed-breed male and female calves with clinical BRD were enrolled. Calves were administered a single subcutaneous dose of either Pradalex at 10 mg/kg body weight or an equivalent volume of sterile saline. Calves were evaluated for clinical success on Day 10. The success rate of Pradalex-treated calves (49.7%) was statistically significantly different (p = 0.0089) and numerically greater than that of saline-treated calves (25.6%) (based on back-transformed least squares means). No adverse events associated with Pradalex administration were reported in the study.

Swine: The effectiveness of Pradalex for the treatment of SRD associated with *Bordetella bronchiseptica*, *Glaesserella* (*Haemophilus) parasuis*, *Pasteurella multocida*, *Streptococcus suis*, and *Mycoplasma hyopneumoniae* was demonstrated in a multi-site, natural infection field study conducted in the U.S. A total of 1,200 castrated male and female growing pigs with clinical SRD were enrolled. At enrollment, pigs were administered a single intramuscular dose of either Pradalex at 7.5 mg/kg body weight, or an equivalent volume of sterile saline. Pigs were evaluated for clinical success on Day 7. The success rate of Pradalex-treated pigs (45.2%) was statistically significantly different (p=0.0274) and numerically greater than that of the saline-treated pigs (34.2%) (based on least squares means). No adverse events associated with Pradalex administration were reported in the study.

A total of 72 castrated male and female growing pigs were enrolled in an *M. hyopneumoniae*-induced challenge model study. Pigs were inoculated with a field strain of *M. hyopneumoniae* once daily for three consecutive days. Three days after the final inoculation, pigs were administered a single intramuscular dose of either Pradalex at 7.5 mg/kg body weight, or an equivalent volume of sterile saline. Pigs were euthanized and necropsied on Day 10. There was a significant difference (p=0.0002) in the mean total lung lesion score in favor of Pradalex-treated pigs (11.7%) compared to the saline-treated pigs (33.1%).

TARGET ANIMAL SAFETY

Cattle: Pradalex was evaluated in a margin of safety study with 32 healthy, weaned calves. Calves were randomized to four treatment groups: 0X (saline control), 1X (10 mg pradofloxacin/kg), 3X (30 mg pradofloxacin/kg) and 5X (50 mg pradofloxacin/kg). Calves were administered subcutaneous doses on Days 0, 4, and 8. All calves remained clinically normal throughout the in-life study and survived until scheduled necropsy on Day 9. Injection site swelling was noted in the 1X and 5X groups. Neutrophil counts, monocyte counts, and creatine kinase levels were generally higher in the treated groups, and this was attributed to inflammation and tissue damage at the injection sites. At necropsy, injection site lesions consisting of discoloration and edema, with microscopically visible hemorrhage, inflammation, and necrosis were reported in most treated animals. No signs of fluoroquinolone-induced arthropathy were reported. No other clinically significant adverse effects related to Pradalex were reported.

Pradalex was also evaluated in a margin of safety study focusing on pathologic changes to the testes and epididymides in 16 healthy, weaned bull calves. Calves were randomized to four treatment groups: 0X (saline control), 1X (10 mg pradofloxacin/kg), 3X (30 mg pradofloxacin/kg) and 5X (50 mg pradofloxacin/kg). Calves were administered subcutaneous doses on Days 0, 4, and 8. All calves remained clinically normal throughout the study and survived until scheduled castration on Day 9. Injection site swelling was noted in the 1X, 3X, and 5X groups. In the 1X group, 3 of 4 calves developed mild to moderate subcutaneous swellings, one resolved by 6 hours post-treatment and two were not resolved by the end of the study. No abnormal macroscopic or microscopic pathology in the testes or epididymides was reported.

Swine: Pradalex was evaluated in a margin of safety study with 32 healthy, weaned, crossbred pigs. Pigs were randomized to four treatment groups: 0X (saline control), 1X (7.5 mg pradofloxacin/kg), 3X (22.5 mg pradofloxacin/kg) and 5X (37.3mg pradofloxacin/kg). Pigs were administered intramuscular doses on Days 0, 2, and 4. All pigs remained clinically normal throughout the in-life study and all pigs survived until scheduled necropsy on Day 11. Aspartate aminotransferase (AST) and creatine phosphokinase (CK) showed elevations and statistically significant treatment by day interactions in Pradalex-treated pigs. These were attributed to inflammation and tissue damage at the injection sites and the values returned to normal by Day 10. There were no other clinically relevant effects on the remaining clinical pathology results. At necropsy, the only macroscopic and microscopic lesions attributable to Pradalex were related to tissue injury at the intramuscular injection sites. No signs of fluoroquinolone-induced arthropathy were reported. No other clinically significant adverse effects related to Pradalex were reported.

STORAGE CONDITIONS

Protect from direct sunlight. Do not refrigerate or freeze. Store at 25ºC (77ºF), excursions permitted up to 40ºC (104ºF) and down to -20ºC (-4ºF).
See in-use instructions provided in the Dosage and Administration section.

HOW SUPPLIED

200 mg/mL 250 mL bottles
200 mg/mL 100 mL bottles

Pradalex is protected by one or more U.S. patents: see patent information at http://www.elancopatents.com

Approved by FDA under NADA # 141-550

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Product of Germany

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TAKE TIME

OBSERVE LABEL DIRECTIONS