Elanco

Pradalex™ (pradofloxacin injection)

TECH SHEET

WHEN IT COMES TO BRD, TIME IS OF THE ESSENCE

STOP BRD BACTERIA BY KILLING THEM THE FIRST TIME WITH Pradalex® (pradofloxacin injection)

Pradalex is an innovative third generation fluoroquinolone antibiotic approved by the FDA in 2024 for the treatment of bovine respiratory disease (BRD).

Pradofloxacin, the active ingredient in Pradalex, features a unique mode of action which targets and inactivates two enzymes responsible for DNA replication with equal affinity in the same organism.

The dual-targeting effect yields improved potency and a broader spectrum of activity relative to other fluroquinolone antibiotics, enabling cattle to get back to health sooner.[1]

ARMOR ID #	DESCRIPTION
34654	PRADALEX INJ 100 ML
34655	PRADALEX INJ 250 ML

RAPID* ABSORPTION: Pradalex reaches maximum therapeutic concentration levels in the plasma in 45 minutes and kills targeted bacteria at achievable concentrations within 5 minutes.

OPTIMIZED PHARMACOKINETICS: Pradalex spends only 8 hours in the mutant selection window (MSW), reducing the risk of selecting for antimicrobial resistance during therapy. Then, it is quickly excreted from the body allowing for a 4-day slaughter withdrawal.

GUIDELINES & LABEL DIRECTIONS

INDICATIONS: 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.

ADMINISTRATION: 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.

STORAGE: Protect from direct sunlight. Do not refrigerate or freeze. Store at 25ºC (77ºF), excursions permitted up to 40ºC (104ºF) and down to -20ºC (-4ºF). The label contains complete use information, including cautions and warnings. Always read, understand and follow the label and use directions.

IMPORTANT SAFETY INFORMATION (ISI): Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Not for use in humans. Keep out of reach of children. Avoid contact with eyes and skin. Individuals with a history of hypersensitivity to quinolones should avoid this product. Not for use in animals intended for breeding greater than 1 year of age because the effects of Pradalex on bovine reproductive performance, pregnancy, and lactation have not been determined. Not for use in beef and dairy calves less than 2 months of age, and veal calves; a withdrawal period has not been established for this product in pre-ruminating calves. Quinolones should be used with caution in animals with known or suspected central nervous system (CNS) disorders. Mild to moderate inflammatory changes of the injection site may be seen in cattle treated with Pradalex. See package insert for additional safety information.

[1] Elanco Animal Health. Data on File.
*Clinical relevance unknown

Elanco™

CONTACT US

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ARMOR ANIMAL HEALTH®
Division of VSI

PRESCRIBING INFORMATION FOR USE IN CATTLE ONLY

Elanco™ Pradalex™
(pradofloxican 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.

Before using Pradalex, please consult the product insert, a summary of which follows:

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.

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

See product insert for complete dosing and administration information.

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. 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.

ANIMAL SAFETY WARNINGS
Not for use in animals intended for breeding because the effects of Pradalex on bovine reproductive performance, pregnancy, and lactation have not been determined.

ADVERSE REACTIONS
Mild to moderate inflammatory changes of the injection site may be seen in cattle 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.

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.

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

TAKE TIME

OBSERVE LABEL DIRECTIONS

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

Product of Germany

Manufactured by TriRx Pharmaceutical Services,
Shawnee Mission, Kansas 66216 U.S.

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