

2026 Q4

YEAR END PRODUCER REBATE

NOVEMBER 2 - DECEMBER 18, 2026

STOCK UP FOR WINTER WITH YEAR-END REWARDS ON PRADALEX™ (PRADOFLOXACIN INJECTION) AND INCREXXA™ (TULATHROMYCIN INJECTION)

QUALIFYING PRODUCT	PURCHASE	ADDITIONAL SAVINGS
Increxxa™ (tulathromycin injection) 250mL	Purchase 1 case of either 250mL or 500mL	**Buy 1 case of Increxxa receive 50% off to qualify for 1 case of Pradalex with a 7% rebate.** **1:1 Match: Every case of Increxxa unlocks an additional qualifying case of Pradalex.**
Increxxa™ (tulathromycin injection) 500mL		
	OR	
Increxxa™ (tulathromycin injection) 100mL	Purchase 2 cases of 100mL	

Elanco™ Pradalex™ (pradofloxacin injection)™



Elanco Increxxa™ (tulathromycin injection)™



CLAIM YOUR REBATE!
ElancoCattleRebates.com

Right for cattle. Right by you.

Elanco™

Ways to Claim Your Rebate:

1. Online Claims: Scan the QR code to be directed to the rebate account set up form to create a rebate account and submit your rebate claims, or visit ElancoCattleRebates.com
2. Mail-in Claims: Complete a mail-in claim form and submit with proof of purchase (invoice) via mail.
3. Supplier Reported Claims (EDI): Qualifying purchases billed through an EDI-reporting distributor will be aggregated at the end of the program. EDI-reporting distributor must report EDI sales to Elanco. Qualifying customers will automatically receive a rebate check in the mail.

Program Terms:

- Beef and dairy producers only are eligible for this program. Veterinarians, resellers, and swine producers are ineligible. Producers enrolled in any special Elanco pricing programs or purchases on Increxxa™ (tulathromycin injection) and Pradalex™ (pradofloxacin injection) below Elanco's minimum advertised price are not eligible for this rebate offer.
- Purchases are cumulative November 2 - December 18, 2026.
- $50 minimum rebate check.
- EDI Purchases over $500 will be paid automatically if the check is a minimum of $50.
- Any EDI purchases under $500 during the program period will not be automatically paid and require submission of an online or mail in claim to receive a rebate if the $50 minimum is hit.
- Allow at minimum 6 weeks for processing following program conclusion.
- Eligible products for the offer include: Increxxa™ (tulathromycin injection) and Pradalex™ (pradofloxacin injection). Offers valid while supplies last.
- **Products that are on backorder and qualify for the rebate offer must ship during the program term to receive the rebate. Products that are on backorder and do not ship during the program term will not qualify for any rebate in this program. All product returns will be applied toward the subsequent program payout period.**
- Producers who submit coupons via mail or online will not be eligible for EDI reported claims.
- Limit 10 mail or online claim submissions per household. Multiple proofs of purchase can be used per submission. One rebate will be calculated per submission. Qualifying rebates will be calculated for all invoices included in a submission and will not be calculated across multiple submissions.
- Mail and online rebate claim form and invoice(s) must be postmarked or submitted by January 18, 2027.
- Elanco reserves the right to vary the terms and conditions of this program or to cancel this program at any time upon notice through the website Elanco.com.
- VOID WHERE PROHIBITED

For more information regarding this rebate program and eligibility, contact your Elanco Animal Health representative or email us at ElancoConsumerRebates@apfco.com

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IMPORTANT SAFETY INFORMATION
For all products: The label contains complete use information, including cautions and warnings. Always read, understand and follow the labels and use directions.

INDICATIONS FOR INCREXXA
Beef and Non-Lactating Dairy Cattle: Treatment of bovine respiratory disease (BRD) and control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni* and *M. bovis*. Treatment of infectious bovine keratoconjunctivitis (IBK) associated with *M. bovis*. Treatment of bovine foot rot (interdigital necrobacillosis) associated with *F. necrophorum* and *P. levii*.
Suckling Calves, Dairy Calves and Veal Calves: Treatment of BRD associated with *M. haemolytica*, *P. multocida*, *H. somni* and *M. bovis*.

IMPORTANT SAFETY INFORMATION FOR INCREXXA
Not for human use. Keep out of reach of children. Do not use in animals previously found to be hypersensitive to the drug. Increxxa has a pre-slaughter withdrawal time of 18 days. Do not use in female dairy cattle 20 months of age or older. See package insert for additional safety information

INDICATIONS FOR PRADALEX
Pradalex is indicated for the treatment of bovine respiratory disease (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.

IMPORTANT SAFETY INFORMATION FOR PRADALEX
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian and 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 only after consideration of other non-fluoroquinolone therapeutic options.
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. 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. 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.
Pradalex has a pre-slaughter withdrawal time of 4 days for cattle. See package insert for additional safety information.

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Right for cattle. Right by you.

Elanco™

CALCULATE YOUR REBATE SAVINGS:

Qualifying Product	*Units Purchased*		*Price Paid Per Unit*		*Rebate %*		*Total Rebate Earned*
ANTI-INFECTIVES							
Increxxa™ 100 mL	Bottles:	X	$	X	50%	=	$
Increxxa™ 250 mL	Bottles:	X	$	X	50%	=	$
Increxxa™ 500 mL	Bottles:	X	$	X	50%	=	$
Pradalex™ 100 mL	Bottles:	X	$	X	7%	=	$
Pradalex™ 250 mL	Bottles:	X	$	X	7%	=	$
					TOTAL REBATE CLAIMED		$

Buy 1 case of Increxxa receive 50% off to qualify for 1 case of Pradalex with a 7% rebate.
1:1 Match: Every case of Increxxa unlocks an additional qualifying case of Pradalex eligible for the 7% rebate.

Submit rebate claim form and invoice(s)
POSTMARKED NO LATER THAN January 18, 2027, to:

2026 Year End Producer Rebate
PO Box 1080
Dept R14797
Grand Rapids, MN 55745-1080

Invoice copy(ies) or invoice statement(s) must accompany this form to obtain rebate.
Invoices or statements must clearly show:

1. Product name(s), product size(s) and date(s) purchased.
2. Name of company where product(s) was/were purchased and price paid.
3. Limit of 10 mail or online claim submissions per household.

Producer Name

Physical Address

Mailing Address

City **State** **Zip**

Phone Number

Email Address

All contact information fields are mandatory.
Elanco reserves the right not to accept claims with incomplete contact information.

☐ I would like to receive future communications from Elanco about farm animal products.

Elanco™ Increxxa™ (tulathromycin injection)

Injectable Solution

Antibiotic

100 mg of tulathromycin/mL

For use in beef cattle (including suckling calves), non-lactating dairy cattle (including dairy calves), veal calves, and swine. Not for use in female dairy cattle 20 months of age or older.

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

DESCRIPTION

Increxxa Injectable Solution is a ready-to-use sterile parenteral preparation containing tulathromycin, a semi-synthetic macrolide antibiotic of the subclass triamilide. Each mL of Increxxa contains 100 mg of tulathromycin, 500 mg propylene glycol, 19.2 mg citric acid and 5 mg monothioglycerol. Sodium hydroxide or hydrochloric acid may be added to adjust pH. Increxxa consists of an equilibrated mixture of two isomeric forms of tulathromycin in a 9:1 ratio.

INDICATIONS

Beef and Non-Lactating Dairy Cattle

BRD – Increxxa Injectable Solution is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*; and for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*.

IBK – Increxxa Injectable Solution is indicated for the treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis*.

Foot Rot – Increxxa Injectable Solution is indicated for the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii*.

Suckling Calves, Dairy Calves, and Veal Calves

BRD – Increxxa Injectable Solution is indicated for the treatment of BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*.

Swine

Increxxa Injectable Solution is indicated for the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*; and for the control of SRD associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, and *Mycoplasma hyopneumoniae* in groups of pigs where SRD has been diagnosed.

DOSAGE AND ADMINISTRATION

Cattle

Inject subcutaneously as a single dose in the neck at a dosage of 2.5 mg/kg (1.1 mL/100 lb) body weight (BW). Do not inject more than 10 mL per injection site.

Table 1. Increxxa Cattle Dosing Guide

Animal Weight (Pounds)	Dose Volume (mL)
100	1.1
200	2.3
300	3.4
400	4.5
500	5.7
600	6.8
700	8.0
800	9.1
900	10.2
1000	11.4

Swine

Inject intramuscularly as a single dose in the neck at a dosage of 2.5 mg/kg (0.25 mL/22 lb) BW. Do not inject more than 2.5 mL per injection site.

Table 2. Increxxa Swine Dosing Guide

Animal Weight (Pounds)	Dose Volume (mL)
15	0.2
30	0.3
50	0.6
70	0.8
90	1.0
110	1.3
130	1.5
150	1.7
170	1.9
190	2.2
210	2.4
230	2.6
250	2.8
270	3.1
290	3.3

CONTRAINDICATIONS

The use of Increxxa Injectable Solution is contraindicated in animals previously found to be hypersensitive to the drug.

WARNINGS

FOR USE IN ANIMALS ONLY.
NOT FOR HUMAN USE.
KEEP OUT OF REACH OF CHILDREN.
NOT FOR USE IN CHICKENS OR TURKEYS.

RESIDUE WARNINGS

Cattle

Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

Swine

Swine intended for human consumption must not be slaughtered within 5 days from the last treatment.

PRECAUTIONS

Cattle

The effects of Increxxa on bovine reproductive performance, pregnancy, and lactation have not been determined. Subcutaneous injection can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.

Swine

The effects of Increxxa on porcine reproductive performance, pregnancy, and lactation have not been determined. Intramuscular injection can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.

ADVERSE REACTIONS

Cattle

In one BRD field study, two calves treated with tulathromycin injection at 2.5 mg/kg BW exhibited transient hypersalivation. One of these calves also exhibited transient dyspnea, which may have been related to pneumonia.

Swine

In one field study, one out of 40 pigs treated with tulathromycin injection at 2.5 mg/kg BW exhibited mild salivation that resolved in less than four hours.

POST APPROVAL EXPERIENCE

The following adverse events are based on post approval adverse drug experience reporting. Not all adverse events are reported to the FDA CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data. The following adverse events are listed in decreasing order of reporting frequency in cattle: Injection site reactions and anaphylaxis/anaphylactoid reactions. 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

At physiological pH, tulathromycin (a weak base) is approximately 50 times more soluble in hydrophilic than hydrophobic media. This solubility profile is consistent with the extracellular pathogen activity typically associated with the macrolides.[1] Markedly higher tulathromycin concentrations are observed in the lungs as compared to the plasma. The extent to which lung concentrations represent free (active) drug was not examined. Therefore, the clinical relevance of these elevated lung concentrations is undetermined. Although the relationship between tulathromycin and the characteristics of its antimicrobial effects has not been characterized, as a class, macrolides tend to be primarily bacteriostatic, but may be bactericidal against some pathogens.[2] They also tend to exhibit concentration independent killing; the rate of bacterial eradication does not change once serum drug concentrations reach 2 to 3 times the minimum inhibitory concentration (MIC) of the targeted pathogen. Under these conditions, the time that serum concentrations remain above the MIC becomes the major determinant of antimicrobial activity. Macrolides also exhibit a post-antibiotic effect (PAE), the duration of which tends to be both drug and pathogen dependent. In general, by increasing the macrolide concentration and the exposure time, the PAE will increase to some maximal duration. Of the two variables, concentration and exposure time, drug concentration tends to be the most powerful determinant of the duration of PAE. Tulathromycin is eliminated from the body primarily unchanged via biliary excretion.

[1] *Carbon, C. 1998. Pharmacodynamics of Macrolides, Azalides, and Streptogramins: Effect on Extracellular Pathogens. Clin. Infect. Dis., **27**:28-32.*

[2] *Nightingale, C.J. 1997. Pharmacokinetics and Pharmacodynamics of Newer Macrolides. Pediatr. Infect. Dis. J., **16**:438-443.*

Cattle

Following subcutaneous administration into the neck of feeder calves at a dosage of 2.5 mg/kg BW, tulathromycin is rapidly and nearly completely absorbed. Peak plasma concentrations generally occur within 15 minutes after dosing and product relative bioavailability exceeds 90%. Total systemic clearance is approximately 170 mL/hr/kg. Tulathromycin distributes extensively into body tissues, as evidenced by volume of distribution values of approximately 11 L/kg in healthy ruminating calves.[3] This extensive volume of distribution is largely responsible for the long elimination half-life of this compound [approximately 2.75 days in the plasma (based on quantifiable terminal plasma drug concentrations) versus 8.75 days for total lung concentrations (based on data from healthy animals)]. Linear pharmacokinetics are observed with subcutaneous doses ranging from 1.27 mg/kg BW to 5.0 mg/kg BW. No pharmacokinetic differences are observed in castrated male versus female calves.

[3] *Clearance and volume estimates are based on intersubject comparisons of 2.5 mg/kg BW administered by either subcutaneous or intravenous injection.*

Swine

Following intramuscular administration to feeder pigs at a dosage of 2.5 mg/kg BW, tulathromycin is completely and rapidly absorbed (T_{max} ~0.25 hour). Subsequently, the drug rapidly distributes into body tissues, achieving a volume of distribution exceeding 15 L/kg.

The free drug is rapidly cleared from the systemic circulation ($CL_{systemic}$= 187 mL/hr/kg). However, it has a long terminal elimination half-life (60 to 90 hours) owing to its extensive volume of distribution. Although pulmonary tulathromycin concentrations are substantially higher than concentrations observed in the plasma, the clinical significance of these findings is undetermined. There are no gender differences in swine tulathromycin pharmacokinetics.

MICROBIOLOGY

Cattle

Tulathromycin has demonstrated *in vitro* activity against *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*, four pathogens associated with BRD; against *Moraxella bovis* associated with IBK; and against *Fusobacterium necrophorum* and *Porphyromonas levii* associated with bovine foot rot.

The MICs of tulathromycin against indicated BRD and IBK pathogens were determined using methods recommended by the Clinical and Laboratory Standards Institute (CLSI, M31-A2). The MICs against foot rot pathogens were also determined using methods recommended by the CLSI (M11-A6). All MIC values were determined using the 9:1 isomer ratio of this compound.

BRD - The MICs of tulathromycin were determined for BRD isolates obtained from calves enrolled in therapeutic and at-risk field studies in the U.S. in 1999. In the therapeutic studies, isolates were obtained from pre-treatment nasopharyngeal swabs from all study calves, and from lung swabs or lung tissue of saline-treated calves that died. In the at-risk studies, isolates were obtained from nasopharyngeal swabs of saline-treated non-responders, and from lung swabs or lung tissue of saline-treated calves that died. The results are shown in Table 3.

IBK - The MICs of tulathromycin were determined for *Moraxella bovis* isolates obtained from calves enrolled in IBK field studies in the U.S. in 2004. Isolates were obtained from pre-treatment conjunctival swabs of calves with clinical signs of IBK enrolled in the tulathromycin injection and saline-treated groups. The results are shown in Table 3.

Foot Rot - The MICs of tulathromycin were determined for *Fusobacterium necrophorum* and *Porphyromonas levii* obtained from cattle enrolled in foot rot field studies in the U.S. and Canada in 2007. Isolates were obtained from pre-treatment interdigital biopsies and swabs of cattle with clinical signs of foot rot enrolled in the tulathromycin injection and saline-treated groups. The results are shown in Table 3.

Table 3. Tulathromycin minimum inhibitory concentration (MIC) values* for indicated pathogens isolated from field studies evaluating BRD and IBK in the U.S. and from foot rot field studies in the U.S. and Canada.

Indicated pathogen	Date isolated	No. of isolates	MIC_{50} ** (µg/mL)	MIC_{90} ** (µg/mL)	MIC range (µg/mL)
Mannheimia haemolytica	1999	642	2	2	0.5 to 64
Pasteurella multocida	1999	221	0.5	1	0.25 to 64
Histophilus somni	1999	36	4	4	1 to 4
Mycoplasma bovis	1999	43	0.125	1	≤ 0.063 to > 64
Moraxella bovis	2004	55	0.5	0.5	0.25 to 1
Fusobacterium necrophorum	2007	116	2	64	≤ 0.25 to > 128
Porphyromonas levii	2007	103	8	128	≤ 0.25 to > 128

* 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

In vitro activity of tulathromycin has been demonstrated against *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*.

The MICs of tulathromycin against indicated SRD pathogens were determined using methods recommended by the Clinical and Laboratory Standards Institute (CLSI, M31-A and M31-A3). MICs for *Haemophilus parasuis* were determined using Veterinary Fastidious Medium and were incubated up to 48 hours at 35 to 37°C in a CO_2-enriched atmosphere.

All MIC values were determined using the 9:1 isomer ratio of this compound. Isolates obtained in 2000 and 2002 were from lung samples from saline-treated pigs and non-treated sentinel pigs enrolled in Treatment of SRD field studies in the U.S. and Canada. Isolates obtained in 2007 and 2008 were from lung samples from saline-treated and tulathromycin injection-treated pigs enrolled in the Control of SRD field study in the U.S. and Canada. The results are shown in Table 4.

Table 4. Tulathromycin minimum inhibitory concentration (MIC) values* for indicated pathogens isolated from field studies evaluating SRD in the U.S. and Canada.

Indicated pathogen	Date isolated	No. of isolates	MIC_{50} ** (µg/mL)	MIC_{90} ** (µg/mL)	MIC range (µg/mL)
Actinobacillus pleuropneumoniae	2000-2002	135	16	32	16 to 32
	2007-2008	88	16	16	4 to 32
Haemophilus parasuis	2000-2002	31	1	2	0.25 to > 64
Pasteurella multocida	2000-2002	55	1	2	0.5 to > 64
	2007-2008	40	1	2	≤ 0.03 to 2
Bordetella bronchiseptica	2000-2002	42	4	8	2 to 8

* 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

BRD – In a multi-location field study, 314 calves with naturally occurring BRD were treated with tulathromycin injection. Responses to treatment were compared to saline-treated controls. A cure was defined as a calf with normal attitude/activity, normal respiration, and a rectal temperature of ≤ 104°F on Day 14. The cure rate was significantly higher (P ≤ 0.05) in tulathromycin injection-treated calves (78%) compared to saline-treated calves (24%). There were two BRD-related deaths in the tulathromycin injection-treated calves compared to nine BRD-related deaths in the saline-treated calves. Fifty-two tulathromycin injection-treated calves and 27 saline-treated calves from the multi-location field BRD treatment study had *Mycoplasma bovis* identified in cultures from pre-treatment nasopharyngeal swabs. Of the 52 tulathromycin injection-treated calves, 37 (71.2%) calves were categorized as cures and 15 (28.8%) calves were categorized as treatment failures. Of the 27 saline-treated calves, 4 (14.8%) calves were categorized as cures and 23 (85.2%) calves were treatment failures.

A Bayesian meta-analysis was conducted to compare the BRD treatment success rate in young calves (calves weighing 250 lbs or less and fed primarily a milk-based diet) treated with tulathromycin injection to the success rate in older calves (calves weighing more than 250 lbs and fed primarily a roughage and grain-based diet) treated with tulathromycin injection. The analysis included data from four BRD treatment effectiveness studies conducted for the approval of tulathromycin injection in the U.S. and nine contemporaneous studies conducted in Europe. The analysis showed that the BRD treatment success rate in young calves was at least as good as the BRD treatment success rate in older calves. As a result, tulathromycin injection is considered effective for the treatment of BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis* in suckling calves, dairy calves, and veal calves.

In another multi-location field study with 399 calves at high risk of developing BRD, administration of tulathromycin injection resulted in a significantly reduced incidence of BRD (11%) compared to saline-treated calves (59%). Effectiveness evaluation was based on scored clinical signs of normal attitude/activity, normal respiration, and a rectal temperature of ≤ 104°F on Day 14. There were no BRD-related deaths in the tulathromycin injection-treated calves compared to two BRD-related deaths in the saline-treated calves.

Fifty saline-treated calves classified as non-responders in this study had *Mycoplasma bovis* identified in cultures of post-treatment nasopharyngeal swabs or lung tissue.

Two induced infection model studies were conducted to confirm the effectiveness of tulathromycin injection against *Mycoplasma bovis*. A total of 166 calves were inoculated intratracheally with field strains of *Mycoplasma bovis*. When calves became pyrexic and had abnormal respiration scores, they were treated with either tulathromycin injection (2.5 mg/kg BW) subcutaneously or an equivalent volume of saline. Calves were observed for signs of BRD for 14 days post-treatment, then were euthanized and necropsied. In both studies, mean lung lesion percentages were statistically significantly lower in the tulathromycin injection-treated calves compared with saline-treated calves (11.3% vs. 28.9%, P = 0.0001 and 15.0% vs. 30.7%, P < 0.0001).

IBK – Two field studies were conducted evaluating tulathromycin injection for the treatment of IBK associated with *Moraxella bovis* in 200 naturally-infected calves. The primary clinical endpoint of these studies was cure rate, defined as a calf with no clinical signs of IBK and no corneal ulcer, assessed on Days 5, 9, 13, 17, and 21. Time to improvement, defined as the first day on which a calf had no clinical signs of IBK in both eyes, provided that those scores were maintained at the next day of observation, was assessed as a secondary variable. At all time points, in both studies, the cure rate was significantly higher (P < 0.05) for tulathromycin injection-treated calves compared to saline-treated calves. Additionally, time to improvement was significantly less (P < 0.0001) in both studies for tulathromycin injection-treated calves compared to saline-treated calves.

Foot Rot - The effectiveness of tulathromycin injection for the treatment of bovine foot rot was evaluated in 170 cattle in two field studies. Cattle diagnosed with bovine foot rot were enrolled and treated with a single subcutaneous dose of tulathromycin injection (2.5 mg/kg BW) or an equivalent volume of saline. Cattle were clinically evaluated 7 days after treatment for treatment success, which was based on defined decreases in lesion, swelling, and lameness scores. In both studies, the treatment success percentage was statistically significantly higher in tulathromycin injection-treated calves compared with saline-treated calves (60% vs. 8%, P < 0.0001 and 83.3% vs. 50%, P = 0.0088).

Swine

In a multi-location field study to evaluate the treatment of naturally occurring SRD, 266 pigs were treated with tulathromycin injection. Responses to treatment were compared to saline-treated controls. Success was defined as a pig with normal attitude, normal respiration, and rectal temperature of < 104°F on Day 7. The treatment success rate was significantly greater (P ≤ 0.05) in tulathromycin injection-treated pigs (70.5%) compared to saline-treated pigs (46.1%). *M. hyopneumoniae* was isolated from 106 saline-treated and non-treated sentinel pigs in this study.

Two induced infection model studies were conducted to confirm the effectiveness of tulathromycin injection against *M. hyopneumoniae*. Ten days after inoculation intranasally and intratracheally with a field strain of *M. hyopneumoniae*, 144 pigs were treated with either tulathromycin injection (2.5 mg/kg BW) intramuscularly or an equivalent volume of saline. Pigs were euthanized and necropsied 10 days post-treatment. The mean percentage of gross pneumonic lung lesions was statistically significantly lower (P < 0.0001) for tulathromycin injection-treated pigs than for saline-treated pigs in both studies (8.52% vs. 23.62% and 11.31% vs. 26.42%).

The effectiveness of tulathromycin injection for the control of SRD was evaluated in a multi-location natural infection field study. When at least 15% of the study candidates showed clinical signs of SRD, all pigs were enrolled and treated with tulathromycin injection (226 pigs) or saline (227 pigs). Responses to treatment were evaluated on Day 7. Success was defined as a pig with normal attitude, normal respiration, and rectal temperature of < 104°F. The treatment success rate was significantly greater (P < 0.05) in tulathromycin injection-treated pigs compared to saline-treated pigs (59.2% vs. 41.2%).

ANIMAL SAFETY

Cattle

Safety studies were conducted in feeder calves receiving a single subcutaneous dose of 25 mg/kg BW, or 3 weekly subcutaneous doses of 2.5, 7.5, or 12.5 mg/kg BW. In all groups, transient indications of pain after injection were seen, including head shaking and pawing at the ground. Injection site swelling, discoloration of the subcutaneous tissues at the injection site and corresponding histopathologic changes were seen in animals in all dosage groups. These lesions showed signs of resolving over time. No other drug-related lesions were observed macroscopically or microscopically. An exploratory study was conducted in feeder calves receiving a single subcutaneous dose of 10, 12.5, or 15 mg/kg BW. Macroscopically, no lesions were observed. Microscopically, minimal to mild myocardial degeneration was seen in one of six calves administered 12.5 mg/kg BW and two of six calves administered 15 mg/kg BW.

A safety study was conducted in preruminant calves 13 to 27 days of age receiving 2.5 mg/kg BW or 7.5 mg/kg BW once subcutaneously. With the exception of minimal to mild injection site reactions, no drug-related clinical signs or other lesions were observed macroscopically or microscopically.

Swine
Safety studies were conducted in pigs receiving a single intramuscular dose of 25 mg/kg BW, or 3 weekly intramuscular doses of 2.5, 7.5, or 12.5 mg/kg BW. In all groups, transient indications of pain after injection were seen, including restlessness and excessive vocalization. Tremors occurred briefly in one animal receiving 7.5 mg/kg BW. Discoloration and edema of injection site tissues and corresponding histopathologic changes were seen in animals at all dosages and resolved over time. No other drug-related lesions were observed macroscopically or microscopically.

STORAGE CONDITIONS
Store below 25°C (77°F), with excursions up to 40°C (104°F).
100 mL: Use within 2 months of first puncture and puncture a maximum of 67 times.
If more than 67 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.
250 mL: Use within 2 months of first puncture and puncture a maximum of 100 times.
If more than 100 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.

HOW SUPPLIED
Increxxa (tulathromycin injection) Injectable Solution is available
in the following package sizes:
100 mL vial
250 mL vial
500 mL vial

CONTACT INFORMATION: For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support 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.



Approved by FDA under ANADA # 200-666
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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.

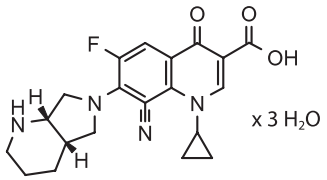
To ensure responsible antimicrobial drug use, use of pradofloxacin should be limited to treatment of bovine respiratory disease (BRD) in cattle and treatment of swine respiratory disease (SRD) in swine only after consideration of other non-fluoroquinolone therapeutic options.

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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