



BEEF PROJECT RECORD BOOK

2026

Name: _____

4-H Club/FFA Chapter/Open: _____

Leader: _____

Age (as of January 1): _____

Years in Project Area: _____

Record Started: _____ / _____ / _____ Record Closed: _____ / _____ / _____
Month Day Year Month Day Year

Check One

☐

Junior:
8-11 years old

☐

Intermediate:
12-14 years old

☐

Senior:
15-19 years old

Record Book Instructions

DON'T CHANGE THE PAPER:

Completed record books must be on standard letter sized (8.5"x11") white paper. There are classes in still exhibits for scrapbook so please leave these types of books there. Minor embellishments are allowed, and neatness is encouraged. Books must be fastened with a staple in the upper right-hand corner or secured inside a 3-ring binder or folder.

DON'T BE LATE.... KNOW THE DUE DATE AND TIME:

The date and time to turn in a completed record book will be listed on the Schedule of Events for Exhibitors.

USE THE RIGHT RESOURCES:

A good resource to help complete this record book includes the publication "Your 4-H Market Beef Project" which is available by loan at the Gratiot County MSU Extension Office. Other resources can be found online.

ONLY COMPLETE YOUR AGE DIVISON:

There are no extra credit points for younger age divisions completing the whole record book.

BREEDING STOCK:

Please fill out the record book to the best of your knowledge for your breeding animal. It is still required for you to fill out the All About My Beef Project, Project Expenses, and Business Plan pages.

All About My Beef Project

For this section use the animal you will most likely exhibit at the fair. If you are exhibiting both market and breeding stock, focus on one registered animal.

Name or identification of my animal: _____

GCFFY Tag Number: _____ RFID Number: _____ Breed: _____

Color(s): _____ Date of birth: _____ Actual BD ____ Estimated ____

Special Markings: _____

Please check one: ____ Purchased ____ Raised Date of purchase: _____

Please check one: ____ Steer ____ Heifer (breeding stock only) ____ Cow ____ Bull

Purchase price: _____

If you raised your animal, list the estimated market value.

A completed record book should have photos of your animal. At a minimum this book should have a beginning and ending picture. Photo captions are encouraged and up to four extra pages of photos can be included in this record book.

Goals and Beef Industry Involvement

What was one goal you had for yourself this year (regarding your beef project)?

What made you choose to exhibit a beef project?

Do you plan to stay involved in the beef industry after aging out of the GCFFY? If yes, how so?

What motivates you to exhibit a quality beef project?

What is a current issue that American beef producers currently face? What are your thoughts on the issue?

Weight Record

The fair recommends all market exhibitors weigh their animals frequently but understands that access to a scale is not always available. A beginning and ending weight should be listed.

It is recommended to weigh your market animals at least once a month. Use one chart for up to four animals. These should be the same four market animals registered on the market beef registration on fair entry.

Animal ID					
Date	Method (scale or tape)	Weight	Weight	Weight	Weight
Final					

Describe changes made based on information you gathered collecting this weight data.

My Project Expenses

List all expenses for this project and record the cost spent under the proper account. If your family/farm is providing feed, please estimate an approximate value. Add additional sheets if necessary. A completed table will have more than one line for each cost. For example, feed costs will need to be itemized as grain, hay, mineral etc.

How many animals are in this project? _____ This can be your project animal and backup animals.					
Date of purchase	Purchase description	Feed Cost	Vet/health Cost	Bedding Cost	Other cost
Total Column Expenses					
Total Project Expenses: (total column expenses)					
Average supply cost per animals (total project expenses divided by number of animals in project)					

My Business Plan:

The following calculations will help you learn about your ability to earn a profit for your participation in this agricultural project. Often in animal projects the profit margin for commercial feeding facilities has a slim profit margin. Let's see how your project would compare.

Average supply cost per animals (from prior page): _____

Purchase cost (primary project animal): _____

Total Expenses (whole project): _____

To calculate total expenses, add average supply cost and primary animal cost.

Finished weight of project animal: _____

Note: finished weight can be taken at home anytime during the week prior to fair or it can be the fair's official market weight.

Break-even price: _____

To calculate the break-even price, divide the total expenses by finished weight.

What is the current market price of market beef? _____

Current beef prices can be found at UProducers.com. Search for market results from St. Louis, MI.

Would you have been able to make a profit if you would have sold your beef animal at the stock yard at this current market price rather than the fair's livestock sale? Why or why not?

Animal Care and Management

Junior, Intermediate, Senior division complete the following:

Describe the pen/pasture you have for your beef animal:

What do you feed your animal? (check all that apply)

☐ Hay ☐ Pellets ☐ Grain ☐ Supplements

☐ Other _____

Please attach your feed tag here to answer questions below.

What is the crude protein percentage in this feed? _____

What is the crude fiber percentage in this feed? _____

What is the main ingredient in this feed? (if not clear, probably the first ingredient listed)

Is this a medicated feed? _____

Your project takes regular care and management. List the things necessary to take care of your project animal(s).

Example: Feeding and watering practices, grooming (clipping, trimming, foot care, etc), health practices, general management (cleaning living area and feed pans, halter breaking, training etc.)

What do your daily responsibilities look like with your animal? Please answer in 3-5 sentences. The more detail the better.

General Fair Knowledge

Junior, Intermediate, Senior division complete the following

Use the fairbook to answer the following questions/fill in the blanks.

SCHEDULE

- What day and time does the beef show start? _____
- When is barn cleanup? _____

EXHIBITOR REQUIREMENTS

- All exhibitors must be between the ages of _____ years old as of January 1 of the current year, unless otherwise noted, and must be residents of _____, a member of a Gratiot County 4-H Club or FFA Chapter, live in a Gratiot County school district or attend a Gratiot County school.

LIVESTOCK REQUIREMENTS

- When is Beef Registration due? _____
- EAR TAG INFORMATION – All cattle, goats and sheep shall bear official _____ identification before they leave their home premises. Swine require official USDA identification prior to being exhibited.
- All animals must be fed, watered and pens cleaned by _____.

MARKET ANIMAL

- Drug testing may be performed on market animals at _____ while on fairgrounds. Any animal found to be in violation, will be _____. All medication/drug _____ requirements must be met by _____. Any animal containing substances at any level not in compliance with United States Food and Drug Administration and/or United States Department of Agriculture Food Safety Inspection Service safety standards; illegal substances and or tampered with animals will be disqualified. Any monies and awards awarded to the individuals, including proceeds will be _____.

BEEF

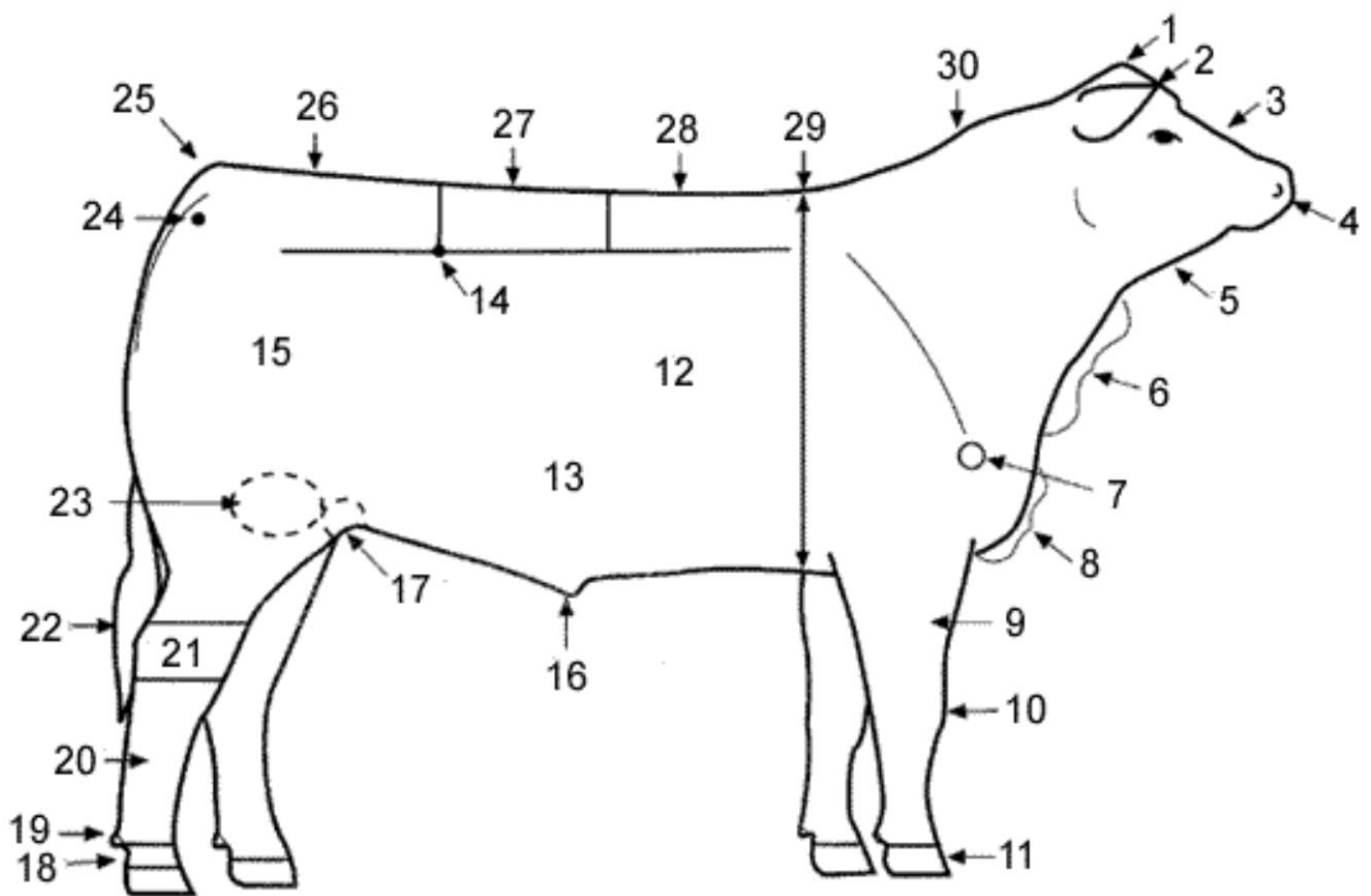
- Market beef must weigh at least _____ lbs. at check-in. Beef below _____ lbs. can be shown in _____ but will not sell.
- What division will you exhibiting your market animal in? _____

General Beef Knowledge

Junior, Intermediate, Senior division complete the following:

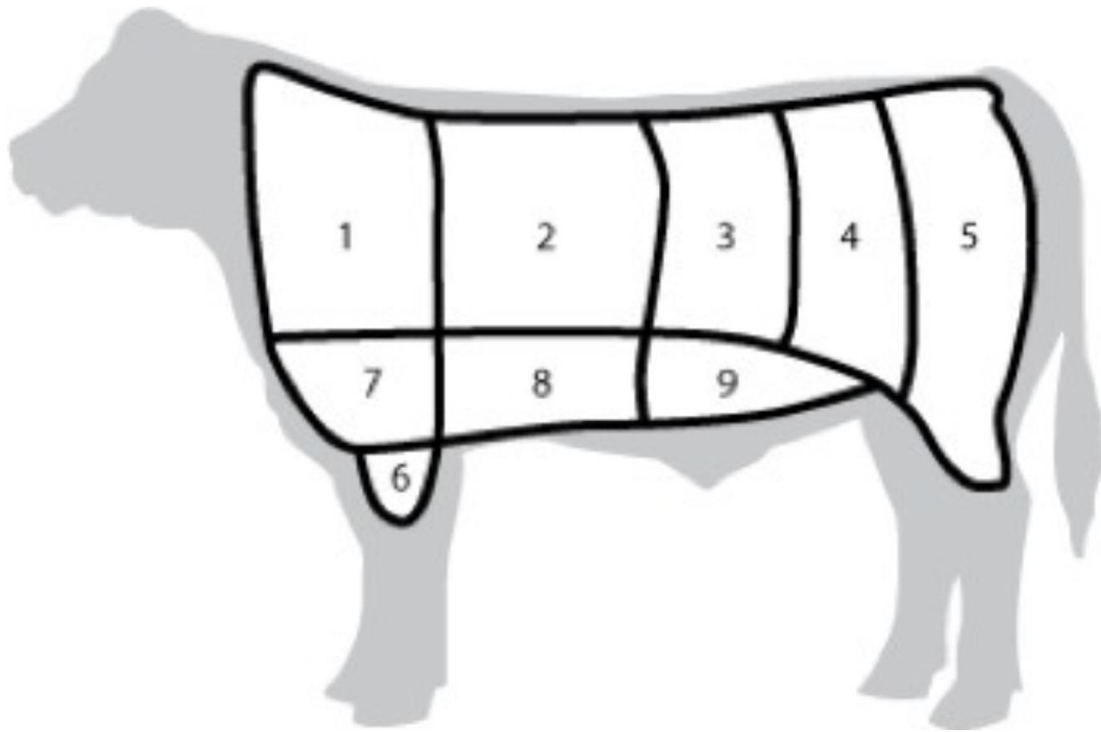
Label the external anatomy to the corresponding number (next page).

Juniors must label any 15 parts and Intermediates and Seniors must label all 30.



1.	16.
2.	17.
3.	18.
4.	19.
5.	20.
6.	21.
7.	22.
8.	23.
9.	24.
10.	25.
11	26.
12.	27.
13.	28.
14.	29.
15.	30.

All divisions must label the wholesale cuts to the corresponding number.



1. _____

6. _____

2. _____

7. _____

3. _____

8. _____

4. _____

9. _____

5. _____

1. Juniors list 2 different beef breeds and a trait that can be found in them. Intermediates and Seniors list 4 beef breeds and a trait that can be found in them.

2. Cattle are known to have a 4-compartment stomach. List the name of each compartment.

3. Intermediates and Seniors ONLY, what kind of digestive system does this mean cattle have?

4. How long is the average gestation period in cattle? What is a gestation period?

5. How long is the average estrus cycle in cattle?

6. What is the average weight of a finished beef animal?

7. What is the average temperature for a mature beef animal?

8. What is a by-product? Name a beef by-product and where it comes from.

9. Intermediates and Seniors ONLY, what is biosecurity and how can YOU take precautions during fair week to ensure proper biosecurity?

Medication Label Questions

Intermediate, Senior Division Complete the following:

Read the Medication Label on the following page and answer the following questions:

1. What is the name of this medication? _____
2. What type of medication is this? _____
3. What is this medication used to treat? _____
4. How should this medication be administered? _____
5. Where should this medication be administered? _____
6. What is the recommended dosage for cattle? _____
7. What dosage would you give a 200lbs calf? _____
8. Looking at the temperature at which this medication should be stored. Where would be a good location to store it?

Draxxin® 25 (tulathromycin injection) Injectable Solution

Antibiotic

25 mg of tulathromycin/mL

For use in suckling calves, dairy calves, veal calves, and swine. Not for use in ruminating cattle.

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

DESCRIPTION

DRAXXIN 25 Injectable Solution is a ready-to-use sterile parenteral preparation containing tulathromycin, a semi-synthetic macrolide antibiotic of the subclass triamidine. Each mL of DRAXXIN 25 contains 25 mg of tulathromycin as the free base in a 50% propylene glycol vehicle, monothioglycerol (5 mg/mL), citric acid (4.8 mg/mL) with hydrochloric acid and sodium hydroxide added to adjust pH. DRAXXIN 25 consists of an equilibrated mixture of two isomeric forms of tulathromycin in a 9:1 ratio.

The chemical names of the isomers are (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[[[2,6-dideoxy-3-C-methyl-3-O-methyl-4-C-[(propylamino) methyl]-α-L-ribohexopyranosyl]oxy]-2-ethyl-3,4,10-trihydroxy-3,5,8,10,12,14-hexamethyl-11-[[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylohexopyranosyl]oxy]-1-oxa-6-azacyclodecan-15-one and (2R,3R,6R,8R,9R,10S,11S,12R)-11-[[[2,6-dideoxy-3-C-methyl-3-O-methyl-4-C-[(propylamino) methyl]-α-L-ribohexopyranosyl]oxy]-2-[[[1R,2R)-1,2-dihydroxy-1-methylbutyl]-8-hydroxy-3,6,8,10,12-pentamethyl-9-[[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylohexopyranosyl]oxy]-1-oxa-4-azacyclodecan-13-one, respectively.

INDICATIONS

Swine

DRAXXIN 25 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.

Suckling Calves, Dairy Calves, and Veal Calves

BRD - DRAXXIN 25 Injectable Solution is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*.

DOSAGE AND ADMINISTRATION

Swine

Inject intramuscularly as a single dose in the neck at a dosage of 2.5 mg/kg (1 mL/22 lb) Body Weight (BW). Do not inject more than 4 mL per injection site.

Table 1. DRAXXIN 25 Swine Dosing Guide (25 mg/mL)

Animal Weight (Pounds)	Dose Volume (mL)
4	0.2
10	0.5
15	0.7
20	0.9
22	1.0
25	1.1
30	1.4
50	2.3
70	3.2
90	4.0

Calves

Inject subcutaneously as a single dose in the neck at a dosage of 2.5 mg/kg (1 mL/22 lb) body weight (BW). Do not inject more than 11.5 mL per injection site.

Table 2. DRAXXIN 25 Calf Dosing Guide (25 mg/mL)

Animal Weight (Pounds)	Dose Volume (mL)
50	2.3
75	3.4
100	4.5
150	7.0
200	9.0
250	11.5

CONTRAINDICATIONS

The use of DRAXXIN 25 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

Swine

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

Calves

Calves intended for human consumption must not be slaughtered within 22 days from the last treatment with DRAXXIN 25 Injectable Solution. This drug is not for use in ruminating cattle.

PRECAUTIONS

Swine

The effects of Draxxin 25 Injectable Solution 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.

Cattle

The effects of Draxxin 25 Injectable Solution 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.

ADVERSE REACTIONS

Swine

In one field study, one out of 40 pigs treated with DRAXXIN Injectable Solution (100 mg/mL) at 2.5 mg/kg BW exhibited mild salivation that resolved in less than four hours.

Calves

In one BRD field study, two calves treated with DRAXXIN Injectable Solution (100 mg/mL) at 2.5 mg/kg BW exhibited transient hypersalivation. One of these calves also exhibited transient dyspnea, which may have been related to pneumonia.

Post Approval Experience

The following adverse events are based on post approval adverse drug experience reporting for DRAXXIN Injectable Solution (100 mg/mL). 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 a complete listing of adverse reactions for DRAXXIN Injectable Solution or DRAXXIN 25 Injectable Solution reported to the CVM see: www.fda.gov/reportanmalae.

CLINICAL PHARMACOLOGY

At physiological pH, tulathromycin (a weak base) is approximately 50 times more soluble in hydrophilic than lipophilic 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 lung parenchyma as compared to the plasma, and these elevated concentrations can remain in lung tissue for several days beyond that which can be measured in the plasma. However the clinical relevance of these elevated lung concentrations is undetermined.

As a class, macrolides tend to be primarily bacteriostatic, but may be bactericidal against some pathogens.² When acting as a cidal compound, they 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.³ 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.

³ Andes D, Anon J, Jacobs MR, Craig WA. (2004). Application of pharmacokinetics and pharmacodynamics to antimicrobial therapy of respiratory tract infections. Clin Lab Med., 24:477-502.

Swine

Following intramuscular (IM) administration to feeder pigs at a dosage of 2.5 mg/kg BW, tulathromycin is nearly completely absorbed, with peak plasma concentrations achieved within ~0.25 hr. The volume of distribution exceeds 15 L/kg, which is consistent with extensive tissue binding. This large distribution volume results in a long terminal elimination half-life (60 to 90 hours) despite a rapid systemic free drug clearance (187 mL/kg/hr). There are no gender differences in swine tulathromycin pharmacokinetics.

Comparative Bioavailability Summary

Despite slightly lower peak concentrations with DRAXXIN 25 Injectable Solution, a single IM dose of 2.5 mg tulathromycin/kg BW of either DRAXXIN Injectable Solution (100 mg/mL) or DRAXXIN 25 Injectable Solution (25 mg/mL) resulted in comparable tulathromycin total systemic exposure. Therefore, DRAXXIN 25 Injectable Solution is considered to be therapeutically equivalent to DRAXXIN Injectable Solution when administered to swine by IM injection at a dose of 2.5 mg tulathromycin/kg BW.

Calves

Following subcutaneous (SC) administration into the neck of feeder calves at a dosage of 2.5 mg/kg BW, tulathromycin is nearly completely absorbed, with peak plasma concentrations achieved within ~0.25 hr. The volume of distribution exceeds 11 L/kg⁴, which is consistent with extensive tissue binding. This large distribution volume results in a long terminal elimination half-life of more than 100 hours, despite a rapid systemic free drug clearance (170 mL/kg/hr). No pharmacokinetic differences are observed in castrated male versus female calves.

Comparative Bioavailability Summary

Despite lower peak concentrations with DRAXXIN 25 Injectable Solution, a single SC dose of 2.5 mg tulathromycin/kg BW of either DRAXXIN Injectable Solution (100 mg/mL) or DRAXXIN 25 Injectable Solution (25 mg/mL) resulted in comparable total systemic tulathromycin exposure. Therefore, DRAXXIN 25 Injectable Solution is considered to be therapeutically equivalent to DRAXXIN Injectable Solution when administered to calves by SC injection at a dose of 2.5 mg tulathromycin/kg BW.

⁴ Clearance and volume estimates are based on intersubject comparisons of 2.5 mg/kg BW administered by either subcutaneous or intravenous injection.

MICROBIOLOGY

Swine

Tulathromycin has demonstrated *in vitro* activity against *A. pleuropneumoniae*, *P. multocida*, *B. bronchiseptica*, *H. parasuis*, and *M. hyopneumoniae*. The MICs of tulathromycin against indicated pathogens collected from field studies were determined using methods recommended by the Clinical and Laboratory Standards Institute (CLSI, M31-A and M31-A3). MICs for *H. parasuis* were determined using Veterinary Fastidious Medium and were incubated up to 48 hours at 35 to 37°C in a CO₂-enriched atmosphere. These values are represented in Table 3, below.

Table 3. 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)
<i>Actinobacillus pleuropneumoniae</i>	2000-2002	135	16	32	16 to 32
	2007-2008	88	16	16	4 to 32
	2000-2002	31	1	2	0.25 to > 64
<i>Haemophilus parasuis</i>					
<i>Pasteurella multocida</i>	2000-2002	55	1	2	0.5 to > 64
	2007-2008	40	1	2	≤ 0.03 to 2
<i>Bordetella bronchiseptica</i>	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.

Calves

Tulathromycin has demonstrated *in vitro* activity against *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*, four pathogens associated with BRD. The MICs of tulathromycin against indicated pathogens collected from field studies using DRAXXIN Injectable Solution (100 mg/mL) were determined using methods recommended by the CLSI (M31-A2). These values are represented in Table 4, below.

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

Indicated pathogen	Date isolated	No. of isolates	MIC ₅₀ ** (µg/mL)	MIC ₉₀ ** (µg/mL)	MIC range (µg/mL)
<i>Mannheimia haemolytica</i>	1999	642	2	2	0.5 to 64
<i>Pasteurella multocida</i>	1999	221	0.5	1	0.25 to 64
<i>Histophilus somni</i>	1999	36	4	4	1 to 4
<i>Mycoplasma bovis</i>	1999	43	0.125	1	≤ 0.063 to > 64

* 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
Swine

Plasma concentrations of tulathromycin administered as DRAXXIN Injectable Solution (100 mg/mL) or as DRAXXIN 25 Injectable Solution were demonstrated to be therapeutically equivalent (see CLINICAL PHARMACOLOGY, Comparative Bioavailability Summary). Therefore effectiveness studies conducted with DRAXXIN Injectable Solution (100 mg/mL) support the effectiveness for DRAXXIN 25 Injectable Solution.

In a multi-location field study to evaluate the treatment of naturally occurring SRD, 266 pigs were treated with DRAXXIN Injectable Solution (100 mg/mL). 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 ($P \leq 0.05$) in DRAXXIN-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 DRAXXIN Injectable Solution (100 mg/mL) against *M. hyopneumoniae*. Ten days after inoculation intranasally and intratracheally with a field strain of *M. hyopneumoniae*, 144 pigs were treated with either DRAXXIN (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 pneumonia lung lesions was statistically significantly lower ($P < 0.0001$) for DRAXXIN-treated pigs than for saline-treated pigs in both studies (8.52% vs. 23.62% and 11.31% vs. 26.42%).

The effectiveness of DRAXXIN Injectable Solution (100 mg/mL) 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 DRAXXIN (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 DRAXXIN-treated pigs compared to saline-treated pigs (59.2% vs. 41.2%).

Calves

Plasma concentrations of tulathromycin administered as DRAXXIN Injectable Solution (100 mg/mL) or as DRAXXIN 25 Injectable Solution were demonstrated to be therapeutically equivalent (see CLINICAL PHARMACOLOGY, Comparative Bioavailability Summary). Therefore effectiveness studies conducted with DRAXXIN Injectable Solution (100 mg/mL) support the effectiveness for DRAXXIN 25 Injectable Solution.

BRD - In a multi-location field study, 314 calves with naturally occurring BRD were treated with DRAXXIN Injectable Solution (100 mg/mL). 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 $\leq 104^\circ\text{F}$ on Day 14. The cure rate was significantly higher ($P \leq 0.05$) in DRAXXIN-treated calves (78%) compared to saline-treated calves (24%). There were two BRD-related deaths in the DRAXXIN-treated calves compared to nine BRD-related deaths in the saline-treated calves.

Fifty-two DRAXXIN Injectable Solution (100 mg/mL)-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 DRAXXIN-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 DRAXXIN Injectable Solution (100 mg/mL) to the success rate in older calves (calves weighing more than 250 lbs and fed primarily a roughage and grain-based diet) treated with DRAXXIN. The analysis included data from four BRD treatment effectiveness studies conducted for the approval of DRAXXIN Injectable Solution (100 mg/mL) 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, DRAXXIN Injectable Solution (100 mg/mL) was 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.

Two induced infection model studies were conducted to confirm the effectiveness of DRAXXIN Injectable Solution (100 mg/mL) against *Mycoplasma bovis*. A total of 166 calves were inoculated intratracheally with field strains of *Mycoplasma bovis*. When calves became pyrexia and had abnormal respiration scores, they were treated with either DRAXXIN (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 DRAXXIN-treated calves compared with saline-treated calves (11.3% vs. 28.9%, $P = 0.0001$ and 15.0% vs. 30.7%, $P < 0.0001$).

ANIMAL SAFETY
Swine

Plasma concentrations of tulathromycin administered as DRAXXIN Injectable Solution (100 mg/mL) or as DRAXXIN 25 Injectable Solution were demonstrated to be therapeutically equivalent (see CLINICAL PHARMACOLOGY, Comparative Bioavailability Summary). Therefore systemic target animal safety studies conducted with DRAXXIN Injectable Solution support the systemic safety for DRAXXIN 25 Injectable Solution.

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 (both studies utilized DRAXXIN Injectable Solution (100 mg/mL)). 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.

Sixteen growing pigs were injected with either saline or DRAXXIN 25 Injectable Solution as a single injection of 4 mL. Injection site observations included two instances of erythema in the DRAXXIN 25-treated group on Day 1 post-injection. No heat, sensitivity, firmness, necrosis, drainage, or swelling was observed at any injection sites in either treatment group. The gross and microscopic findings in the DRAXXIN 25-treated group were consistent with inflammatory changes induced by injections and were considered to be mild or moderate with progression to macroscopic resolution by Day 28 post-injection and microscopic resolution by Day 42 post-injection.

Calves

Plasma concentrations of tulathromycin administered as DRAXXIN Injectable Solution (100 mg/mL) or as DRAXXIN 25 Injectable Solution were demonstrated to be therapeutically equivalent (see CLINICAL PHARMACOLOGY, Comparative Bioavailability Summary). Therefore effectiveness studies conducted with DRAXXIN Injectable Solution support the systemic safety for DRAXXIN 25 Injectable Solution.

A safety study was conducted in feeder calves receiving DRAXXIN Injectable Solution (100 mg/mL) as 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 DRAXXIN Injectable Solution (100 mg/mL) as 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 DRAXXIN Injectable Solution (100 mg/mL) at 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.

Sixteen growing cattle were injected with either saline (eight animals) as a single injection of 11.5 mL or DRAXXIN 25 Injectable Solution (eight animals) as a single injection of either 2.5 mg/kg BW or a dose volume of 11.5 mL (whichever volume was higher). One calf in the DRAXXIN 25-treated group was observed to have firmness at the injection site for a single day. Two DRAXXIN 25-treated calves exhibited injection site swelling. In one calf, the swelling resolved within 48 hours. In the other calf, the swelling was observed over a three-day period, after which the calf underwent a scheduled necropsy, preventing further injection site observations. No injection site swelling was observed in saline-treated animals. At necropsy, three of the saline-treated calves and five of the DRAXXIN 25-treated calves had altered tissue present at the injection site. The gross and microscopic findings in the DRAXXIN 25-treated group were consistent with inflammatory changes induced by injections, were considered to be mild to marked, and progressed to macroscopic resolution and microscopic resolution by Day 42 post-injection.

STORAGE CONDITIONS:

Store at or below 25°C (77°F). Use within 90 days of first vial puncture.

HOW SUPPLIED

DRAXXIN 25 Injectable Solution is available in the following package sizes:

50 mL vial
100 mL vial
250 mL vial

Approved by FDA under NADA # 141-349



Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

To report a suspected adverse reaction or to request a safety data sheet call 1-888-963-8471. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

For additional DRAXXIN 25 product information call: 1-888-DRAXXIN or go to www.DRAXXIN.com



4023411/4025352A&P
Revised: September 2020

Grading – Juniors ONLY

Cover Page _____/8

All About My Beef Project _____/11

Beginning and Ending Photos _____/2

Goals and Beef Industry Involvement _____/6

Weight Record _____/4

My Project Expenses _____/6

My Business Plan _____/8

Animal Care and Management _____/10

General Fair Knowledge _____/17

General Beef Knowledge _____/39

Points possible: 111

Points earned:

Grading – Intermediate and Senior ONLY

Cover Page _____/8

All About My Beef Project _____/11

Beginning and Ending Photos _____/2

Goals and Beef Industry Involvement _____/6

Weight Record _____/4

My Project Expenses _____/6

My Business Plan _____/8

Animal Care and Management _____/10

General Fair Knowledge _____/17

General Beef Knowledge _____/62

Medication Label Questions _____/8

Points possible: 142

Points earned:

Judge's comments:

Tie Breakers

In the event of a tie, judges will determine a tie breaker by how thorough answers are, how neat the entire book is, and overall presentation.