

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-742

Tulathromycin Injection

Injectable Solution

Beef cattle, non-lactating dairy cattle, suckling calves, dairy calves, veal calves, and swine

Beef and Non-Lactating Dairy Cattle

BRD – Tulathromycin Injection 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 – Tulathromycin Injection is indicated for the treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis*.

Foot Rot – Tulathromycin Injection 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 – Tulathromycin Injection is indicated for the treatment of BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*.

Swine

Tulathromycin Injection 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.

Sponsored by:

Hikma Pharmaceuticals USA, Inc.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-742

B. Sponsor

Hikma Pharmaceuticals USA, Inc.
2 Esterbrook Lane
Cherry Hill, NJ 08003
Drug Labeler Code: 086194

C. Proprietary Name

Tulathromycin Injection

D. Drug Product Established Name

tulathromycin injection

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

100 mg of tulathromycin/mL

H. How Supplied

50 mL, 100 mL, 250 mL, and 500 mL vials

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

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.

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.

K. Route of Administration

Subcutaneous injection (cattle) and intramuscular injection (swine)

L. Species/Classes

Beef cattle, non-lactating dairy cattle, suckling calves, dairy calves, veal calves, and swine

M. Indications

Beef and Non-Lactating Dairy Cattle

BRD – Tulathromycin Injection 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 – Tulathromycin Injection is indicated for the treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis*.

Foot Rot – Tulathromycin Injection 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 – Tulathromycin Injection is indicated for the treatment of BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*.

Swine

Tulathromycin Injection 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.

N. Reference Listed New Animal Drug (RLNAD)

Draxxin®; tulathromycin injection; NADA 141-244; Zoetis Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is

demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Hikma Pharmaceuticals USA, Inc., was granted a biowaiver for the generic product Tulathromycin Injection. The generic drug product is an injectable solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is Draxxin® (tulathromycin injection) injectable solution, sponsored by Zoetis Inc., under NADA 141-244, and was approved for use in beef cattle, non-lactating dairy cattle, and swine on May 24, 2005, and suckling calves, dairy calves and veal calves on October 16, 2014.

III. HUMAN FOOD SAFETY

The tolerances for residues and withdrawal periods established for the RLNAD apply to the generic product. The following are assigned to this product for cattle and swine:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of tulathromycin is 15 µg/kg of body weight *per day* (21 CFR 556.745). The tolerances established for the RLNAD apply to the generic product. A tolerance of 5.5 parts *per million* (ppm) is established for CP-60,300 (the marker residue) in cattle liver (the target tissue), and a tolerance of 15 ppm is established for CP-60,300 (the marker residue) in swine kidney (the target tissue), under 21 CFR 556.745.

B. Withdrawal Periods

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 18 days has been established for tulathromycin in beef cattle, non-lactating dairy cattle, suckling calves, dairy calves, and veal calves treated with tulathromycin injection (100 mg/mL) as a single subcutaneous injection in the neck at a dose of 2.5 mg/kg of body weight. A withdrawal period of 5 days has been established for tulathromycin in swine treated with tulathromycin injection (100 mg/mL) as a single intramuscular injection in the neck at a dose of 2.5 mg/kg of body weight.

C. Analytical Method for Residues

The validated analytical methods for analysis of residues of tulathromycin are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical method, please submit a Freedom of Information request to: <https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm>.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Tulathromycin Injection:

**FOR USE IN ANIMALS ONLY.
NOT FOR HUMAN USE.
KEEP OUT OF REACH OF CHILDREN.**

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that Tulathromycin Injection, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.

Additionally, data demonstrate that residues in food products derived from beef cattle, non-lactating dairy cattle, suckling calves, dairy calves, veal calves, and swine treated with Tulathromycin Injection will not represent a public health concern when the product is used according to the label.