Date of Approval: February 7, 2022

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-665

Increxxa™ 25

(tulathromycin injection)

Injectable Solution

Swine, suckling calves, dairy calves, and veal calves

Swine

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

Sponsored by:

Elanco US Inc.

Table of Contents

I. GENERAL INFORMATION

A. File Number

ANADA 200-665

B. Sponsor

Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140
Drug Labeler Code: 058198

Drug Labeler Code: 058198

C. Proprietary Name

Increxxa™ 25

D. Drug Product Established Name

tulathromycin injection

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Injectable Solution

G. Amount of Active Ingredient

25 mg tulathromycin/mL

H. How Supplied

50-mL, 100-mL, and 250-mL vials

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

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.

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

K. Route of Administration

Subcutaneous injection (calves) and intramuscular injection (swine)

L. Species/Class

Swine, suckling calves, dairy calves, and veal calves

M. Indications

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

N. Reference Listed New Animal Drug (RLNAD)

Draxxin® 25; tulathromycin injection; NADA 141-349; 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, Elanco US Inc., was granted a biowaiver for the generic product Increxxa™ 25 (tulathromycin injection) injectable solution. 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® 25 (tulathromycin injection) injectable solution, sponsored by Zoetis Inc., under NADA 141-349, and was approved for use in swine on July 9, 2013 and in suckling calves, dairy calves, and veal calves on November 19, 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 swine and cattle (suckling calves, dairy calves, and veal calves):

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. The tolerances established for the RLNAD apply to the generic product. A tolerance of 5.5 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 22 days has been established for tulathromycin in calves intended for human consumption treated with tulathromycin injection (25 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 (25 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 method for analysis of residues of tulathromycin is 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 Increxxa™ 25:

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 Increxxa™ 25, when used according to the label, is safe and effective for the indications listed in Section I.M. above.

Additionally, data demonstrate that residues in food products derived from swine, suckling calves, dairy calves, and veal calves treated with Increxxa™ 25 will not represent a public health concern when the product is used according to the label.