FULL PRESCRIBING INFORMATION FOR USE IN SWINE ONLY

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

INDICATIONS
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
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 1. 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

See product insert for complete dosing and administration information.

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

PRECAUTIONS
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
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.

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
To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Elanco at 1-800-422-9874. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

Approved by FDA under ANADA # 200-666
Product of China.

Manufactured by: Elanco US Inc, Shawnee, KS 66216
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February, 2021

TAKE TIME

OBSERVE LABEL DIRECTIONS

Elanco™

SEE PRODUCT INSERT FOR COMPLETE DOSING AND ADMINISTRATION INFORMATION.

Elanco™

Increxxa™ 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.

Before using Increxxa 25, please consult the complete product insert, a summary of which follows:

INDICATIONS

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.

DOSAGE AND ADMINISTRATION

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. Increxxa 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

See product insert for complete dosing and administration information.

CONTRAINDICATIONS

The use of Increxxa 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 intended for human consumption must not be slaughtered within 5 days from the last treatment.

PRECAUTIONS

The effects of tulathromycin injection 25 mg/mL 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

Post Approval Experience

The following adverse events are based on post approval adverse drug experience reporting for tulathromycin injection 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 casual relationship to product exposure using these data.

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

Following intramuscular (IM) administration to feeder pigs at a dosage of 2.5 g/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 tulathromycin injection 25 mg/mL, a single IM dose of 2.5 mg tulathromycin/kg BW of either tulathromycin injection 100 mg/mL or tulathromycin injection 25 mg/mL resulted in comparable tulathromycin total systemic exposure. Therefore, tulathromycin injection 25 mg/mL is to be considered therapeutically equivalent to tulathromycin injection 100 mg/ml when administered to swine by IM injection at a dose of 2.4 mg tulathromycin/kg BW.

STORAGE CONDITIONS

50 mL and 100 mL vials: Store at or below 25°C (77°F) with excursions up to 40°C (104°F). Use this product within 90 days of first puncture and puncture a maximum of 9 times. If more than 9 punctures are anticipated, the use of automatic injection equipment or a repeated syringe is recommended. Puncture a maximum of 4 times with a dosage delivery device no larger than 4.75 mm diameter. Any product remaining beyond these parameters should be disgarded.

250 mL vials: Store at or below 25°C (77°F) with excursions up to 40°C (104°F). Use this product within 90 days of first puncture and puncture a maximum of 22 times. If more than 22 punctures are anticipated, the use of automatic injection equipment or a repeated syringe is recommended. Puncture a maximum of 4 times with a dosage delivery device no larger than 4.75 mm in diameter. Any product remaining beyond these parameters should be discarded.

HOW SUPPLIED

Increxxa 25 (tulathromycin injection) Injectable Solution is available in the following package sizes:
50 mL vial
100 mL vial
250 mL vial

Approved by FDA under ANADA # 200-665
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Distributed by: Elanco US Inc.
Greenfield, IN 46140

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact **1-800-428-4441**. For additional information about adverse drug experiences reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

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