Tulissin®-25-
(tulathromycin injection)

- TULISSIN® 25 (tulathromycin injection) is a ready-to-use sterile parenteral preparation containing tulathromycin, a semi-synthetic macrolide antibiotic of the subclass triamilide.
- Each mL of TULISSIN 25 Injectable Solution contains 25 mg of tulathromycin.
- For use by or on the order of a licensed veterinarian.

Swine

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

Dosing/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.

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.

Withdrawal Period:

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 TULISSIN 25 Injectable Solution. This drug is not for use in ruminating cattle.

Take a New Breath

If you trust your herd with tulathromycin, then you need TULISSIN 25 injectable solution.

- **Goes to work in minutes**[1]
- Concentrates in the **most susceptible areas** of the respiratory system
- Provides **nine days** of lung activity to treat and control SRD[2]

TULISSIN 25 injectible solution is formulated for weaned pigs to allow for accurate dosing.

TULISSIN 25 mg/mL for swine: 1 mL/22 lb. BW

Packaging:

Cartons contain either 20 x 100 mL vials or 15 x 250 mL vials.

Storage:

Store at or below 30° C (86° F). Use within 45 days of first puncture and puncture a maximum of 30 times. Consider using automatic injection equipment or a repeater syringe. When using a needle or draw-off spike larger than 16 gauge, discard any remaining product immediately after use.

[1]Villarino N, Brown SA, Martín-Jiménez T. Understanding the pharmacokinetics of tulathromycin: a pulmonary perspective. *J Vet Pharmacol Ther.* 2014;37(3):211-221.

[2]Waag TA, Bradford JR, Lucas MJ, et al. Duration of effectiveness of tulathromycin injectable solution in an Actinobacillus pleuropneumoniae respiratory-disease challenge model in swine. *J Swine Health Prod.* 2008;16(3):126–130.

IMPORTANT SAFETY INFORMATION TULISSIN® 25 (tulathromycin injection):
Not for use in ruminating cattle. Ensure a pre-slaughter withdrawal time of twenty-two (22) days in calves and five (5) days in swine. The effects of tulathromycin on bovine and swine reproductive performance, pregnancy and lactation have not been determined. Do not use in animals known to be hypersensitive to the product.

Marketed by

Pharmgate ANIMAL HEALTH

Virbac Corporation 1301 Solana Boulevard, Building 2, Suite 2400
Westlake, TX 76262. https://vet-us.virbac.com/home.html

Virbac

Shaping the future of animal health

Brief Summary of Prescribing Information for Swine
Before using TULISSIN® 25 (tulathromycin injection) consult the product insert, a summary of which follows:

Virbac Tulissin®25 (tulathromycin injection) Injectable Solution

Antibiotic
25 mg of tulathromycin/mL
For use in swine

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

INDICATIONS:
Swine
TULISSIN 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
Swine
IInject 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. TULISSIN 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

CONTRAINDICATIONS
The use of TULISSIN 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
Swine
The effects of TULISSIN 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.

ADVERSE REACTIONS
Swine
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.

STORAGE CONDITIONS:
Store at or below 30°C (86°F). Use within 45 days of first puncture and puncture a maximum of 30 times. Consider using automatic injection equipment or a repeater syringe. When using a needle or draw-off spike larger than 16 gauge, discard any remaining product immediately after use.

Manufactured for:
Virbac AH, Inc.
P.O. Box 162059, Fort Worth, TX 76161
Made in France

Approved by FDA under ANADA # 200-668

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Virbac AH, Inc. at 1-800-338-3659 or us.virbac.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

TAKE TIME  OBSERVE LABEL DIRECTIONS

Rev. 06/21

Brief Summary of Prescribing Information for Cattle
Before using TULISSIN® 25 (tulathromycin injection) consult the product insert, a summary of which follows:

Virbac Tulissin®25 (tulathromycin injection) Injectable Solution

Antibiotic
25 mg of tulathromycin/mL
For use in suckling calves, dairy calves, and veal calves. Not for use in ruminating cattle.

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

INDICATIONS:
Suckling Calves, Dairy Calves, and Veal Calves
BRD - TULISSIN 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
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 1. TULISSIN 25 Injectable Solution Calf Dosing Guide (25 mg/mL)
(refer to table 2 on product insert)

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

PRECAUTIONS
Cattle
The effects of TULISSIN 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
Calves
In one BRD field study, two calves treated with tulathromycin injection (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 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 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.

STORAGE CONDITIONS:
Store at or below 30°C (86°F). Use within 45 days of first puncture and puncture a maximum of 30 times. Consider using automatic injection equipment or a repeater syringe. When using a needle or draw-off spike larger than 16 gauge, discard any remaining product immediately after use.

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