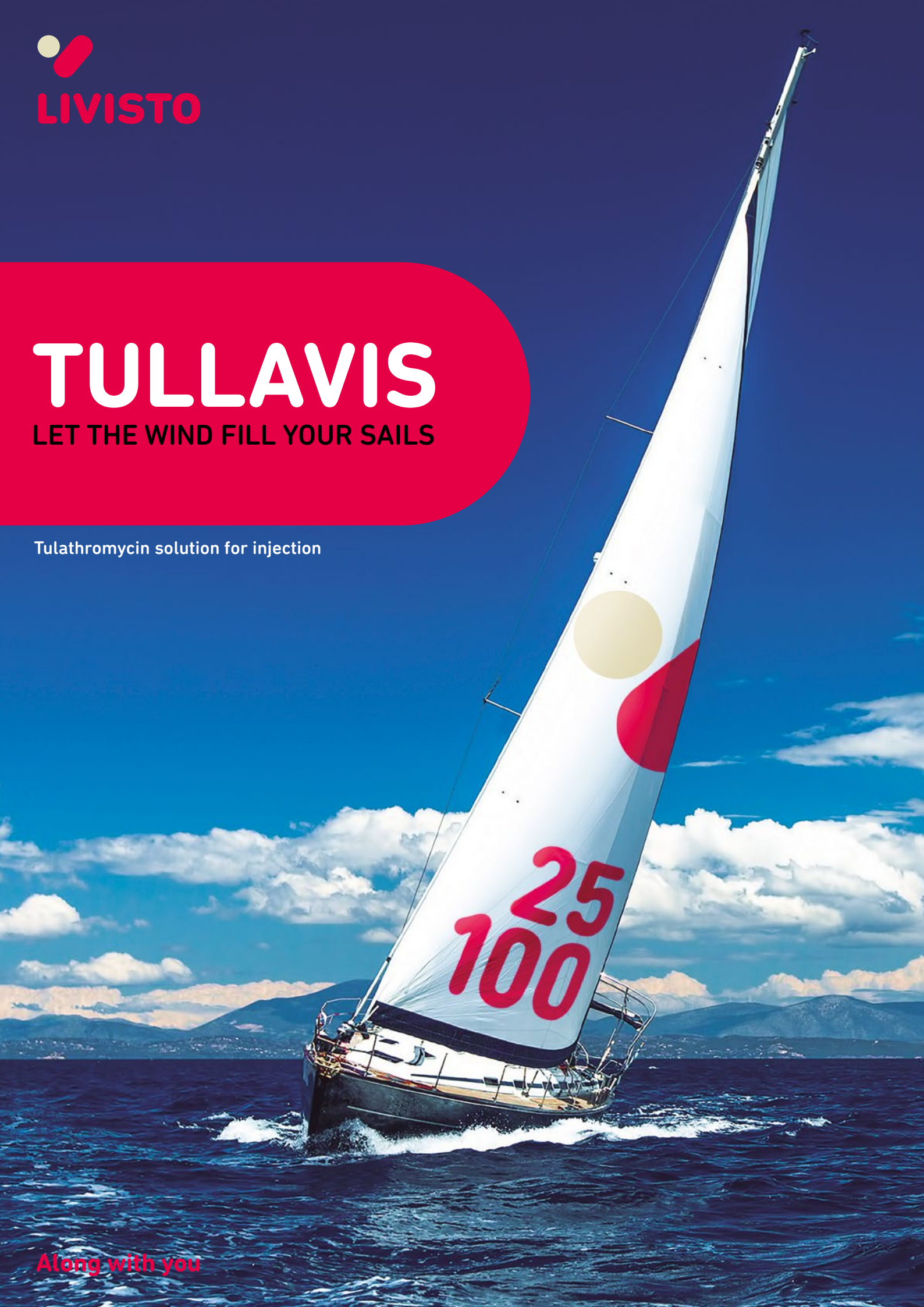
LIVISTO

TULLAVIS

LET THE WIND FILL YOUR SAILS

Tulathromycin solution for injection



Along with you

TULLAVIS 100 mg/ml

Tulathromycin solution for injection for cattle, pigs and sheep

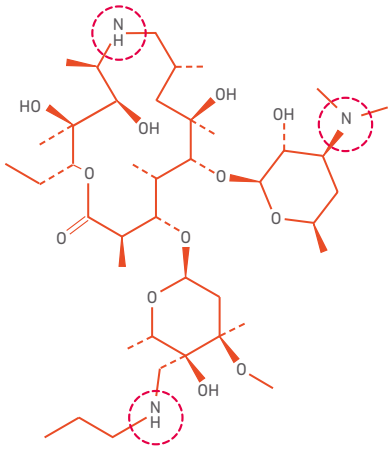
TULLAVIS 25 mg/ml

Tulathromycin solution for injection for pigs

TULATHROMYCIN

Tulathromycin is a is a semi-synthetic macrolide developed exclusively for veterinary use.
The chemical structure of Tulathromycin confers some advantages over other macrolides and other antibiotic groups:

Pharmacological characteristics	Advantage *vs.* other antibiotics	Benefit
Presence of 3 polar amine groups	Longer duration of action.[1,2]	**SINGLE-DOSE TREATMENT**
Molecule with 3 positive charges	Easier penetration into Gram-negative bacteria.[1,3]	**BROAD SPECTRUM ACTIVITY**
Accumulation in inflammatory cells in lung and airway tissue	**Persistence in respiratory tissues** and recruitment of drug-loaded neutrophils and alveolar macrophages into the lung.[1,4]	**ANTI-INFLAMMATORY PROPERTIES** **TARGETED TREATMENT FOR RESPIRATORY DISEASE**



IN RESPIRATORY DISEASE

Macrolides have been widely used for the control of respiratory disease in livestock. Tulathromycin has been proven to have a good efficacy against respiratory disease thanks to its rapid absorption, excellent distribution and bioavailability in lung tissue, and broad spectrum antimicrobial activity including against *Mycoplasma* spp.

LET THE WIND FILL YOUR SAILS

TULLAVIS 100 is a tulathromycin solution for injection for cattle, pigs and sheep.

TULLAVIS 25 is a tulathromycin solution for injection for pigs.

INDICATIONS

DOSE & WITHDRAWAL TIME

TULLAVIS 100

- Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni and Mycoplasma bovis*
- Treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis*.

- Subcutaneous route
- 1 mL/40 kg b.w.
- Single dose

Not authorised for use in animals producing milk for human consumption.

Meat and offal
22 days

TULLAVIS 100

- Treatment of the early stages of infectious pododermatitis (foot rot) associated with virulent *Dichelobacter nodosus* requiring systemic treatment.

- Intramuscular route
- 1 mL/40 kg b.w.
- Single dose

Not authorised for use in animals producing milk for human consumption.

Meat and offal
16 days

TULLAVIS 100 and **TULLAVIS 25**

- Treatment and metaphylaxis of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Mycoplasma hyopneumoniae, Haemophilus parasuis* and *Bordetella bronchiseptica*.

TULLAVIS 100

- Intramuscular route
- 1 mL/40 kg b.w.
- Single dose

TULLAVIS 25

- Intramuscular route
- 1 mL/10 kg b.w.
- Single dose

Meat and offal
13 days

mL of TULLAVIS												
Pigs bodyweight (Kg)	2	6	8	10	20	40	50	60	70	80	100	120
TULLAVIS 100 (mL)	0.05	0.15	0.2	0.25	0.5	1	**1.25**	**1.5**	**1.75**	**2**	**2.5**	**3**
TULLAVIS 25 (mL)	**0.2**	**0.6**	**0.8**	**1**	**2**	**4**	5	6	7	8	10	12

TULLAVIS 25: the most practical and accurate dose for pigs less than 40 kg.

LIVISTO

TULLAVIS 100 mg/ml

Tulathromycin solution for injection for cattle, pigs and sheep

TULLAVIS 25 mg/ml

Tulathromycin solution for injection for pigs

LET THE WIND FILL YOUR SAILS

SINGLE-DOSE TREATMENT

Composition
1ml contains: Tulathromycin 100 mg
Tulathromycin 25 mg

Pharmaceutical form
Solution for injection.
Clear colourless to yellowish solution.

Target species
TULLAVIS 100: cattle, pigs and sheep
TULLAVIS 25: pigs

Indications for use
TULLAVIS 100
Cattle: Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. Treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis* susceptible to tulathromycin.
Pigs: Treatment and metaphylaxis of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Mycoplasma hyopneumoniae*, *Haemophilus parasuis* and *Bordetella bronchiseptica* susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment.
Sheep: Treatment of the early stages of infectious pododermatitis (foot rot) associated with virulent *Dichelobacter nodosus* requiring systemic treatment.

TULLAVIS 25
Pigs: Treatment and metaphylaxis of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Mycoplasma hyopneumoniae*, *Haemophilus parasuis* and *Bordetella bronchiseptica* susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment.

Contraindications
Do not use in known cases of hypersensitivity to the active substance, other macrolides or to any of the excipients. Do not use simultaneously with other macrolides or lincosamides.

Special warnings for each target specie
TULLAVIS 100
Sheep: The efficacy of antimicrobial treatment of foot rot might be reduced by other factors, such as wet environmental conditions, as well as inappropriate farm management. Treatment of foot rot should therefore be undertaken along with other flock management tools, for example providing dry environment. Antibiotic treatment of benign foot rot is not considered appropriate. Tulathromycin showed limited efficacy in sheep with severe clinical signs or chronic foot rot, and should therefore only be given at an early stage of foot rot.
TULLAVIS 25
None.

Special precautions for use
Special precautions for use in animals: Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to tulathromycin and may decrease the effectiveness of treatment with other macrolides, due to the potential for cross resistance. If a hypersensitivity reaction occurs appropriate treatment should be administered without delay.
Special precautions to be taken by the person administering the veterinary medicinal product to animals: Tulathromycin is irritating to eyes. In case of accidental eye exposure, flush the eyes immediately with clean water. Tulathromycin may cause sensitisation by skin contact. In case of accidental spillage onto skin, wash the skin immediately with soap and water. Wash hands after use. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Adverse reactions
TULLAVIS 100
Subcutaneous administration of the product to cattle causes very commonly transient pain reactions and local swellings at the injection site that can persist for up to 30 days. No such reactions have been observed in pigs and sheep after intramuscular administration. Pathomorphological injection site reactions (including reversible changes of congestion, oedema, fibrosis and haemorrhage) are very common for approximately 30 days after injection in cattle and pig. In sheep transient signs of discomfort (head shaking, rubbing injection site, backing away) are very common after intramuscular injection. These signs resolve within a few minutes.
TULLAVIS 25
Pathomorphological injection site reactions (including reversible changes of congestion, oedema, fibrosis and haemorrhage) are present for approximately 30 days after injection.

Use during pregnancy, lactation or lay
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction
Cross resistance occurs with other macrolides. Do not administer simultaneously with antimicrobials with a similar mode of action such as other macrolides or lincosamides.

Amounts to be administered and administration route
Cattle: Subcutaneous use. A single subcutaneous injection of 2.5 mg tulathromycin/kg b.w. (equivalent to 1 ml/40 kg b.w.). For treatment of cattle over 300 kg b.w., divide the dose so that no more than 7.5 ml are injected at one site.
Pigs:
TULLAVIS 100: Intramuscular use. A single intramuscular injection of 2.5 mg tulathromycin/kg b.w. (equivalent to 1 ml/40 kg b.w.) in the neck. For treatment of pigs over 80 kg b.w., divide the dose so that no more than 2 ml are injected at one site.
TULLAVIS 25: Intramuscular use. A single intramuscular injection of 2.5 mg tulathromycin/kg b.w. (equivalent to 1 ml/10 kg b.w.) in the neck. For treatment of pigs over 40 kg b.w., divide the dose so that no more than 4 ml are injected at one site.
Sheep: Intramuscular use. A single intramuscular injection of 2.5 mg tulathromycin/kg b.w. (equivalent to 1 ml/40 kg b.w.) in the neck.
Overdose (symptoms, emergency procedures, antidotes), if necessary
In cattle at dosages of 3, 5 or 10 times the recommended dose, transient signs attributed to injection site discomfort were observed and included restlessness, head-shaking, pawing the ground, and brief decrease in feed intake. Mild myocardial degeneration has been observed in cattle receiving 5 to 6 times the recommended dose. In young pigs weighing approximately 10 kg given 3 or 5 times the therapeutic dose transient signs attributed to injection site discomfort were observed and included excessive vocalisation and restlessness. Lameness was also observed when the hind leg was used as the injection site. In lambs (approx. 6 weeks old), at dosages of 3 or 5 times the recommended dose, transient signs attributed to injection site discomfort were observed, and included walking backwards, head shaking, rubbing the injection site, lying down and getting up, bleating.

Withdrawal periods
TULLAVIS 100
Cattle: Meat and offal: 22 days
Pigs: Meat and offal: 13 days
Sheep: Meat and offal: 16 days
Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals, which are intended to produce milk for human consumption, within 2 months of expected parturition.
TULLAVIS 25
Pigs: Meat and offal: 13 days

Shelf life
Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 28 days.

Special precautions for storage
Do not store above 30 °C.

Packaging
TULLAVIS 100: Glass vials of 50 ml, 100 ml and 250 ml.
TULLAVIS 25: Glass vials of 100 ml and 250 ml.

Marketing authorisation holder
LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès
(Barcelona), Spain

References

1. Evans, N. A. Tulathromycin: an overview of a new triamilide antibiotic for livestock respiratory disease. *Vet. Ther.* 6, 83–95 (2005).
2. EMA. TULLAVIS 100 mg/ml. Summary of product characteristics. (2019).
3. Papich, M. G. Tulathromycin. *Saunders Handb. Vet. Drugs* 824–825 (2016).
4. Kilgore, W. R. et al. Therapeutic efficacy of tulathromycin, a novel triamilide antimicrobial, against bovine respiratory disease in feeder calves. *Vet. Ther.* 6, 143–153 (2005).

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PRUDENT USE OF ANTIBIOTICS

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