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Tulieve 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep

Species: Cattle, Pigs, Sheep

Therapeutic indication:Pharmaceuticals: Antimicrobials: Injections

Active ingredient: Tulathromycin

Product: Tulieve 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep

Product index: Tulieve

Cattle - meat:22 Days

Sheep - meat:16 Days

Pig - meat:13 Days

Withdrawal notes: 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.

Incorporating:

Qualitative and quantitative composition

1 ml contains:

Active substance(s):

Tulathromycin 100 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is es the veterinary medicinal product
Citric Acid (E330)	19.2 mg

Monothioglycerol	5 mg
Citric acid	
Hydrochloric acid, concentrated (pH adjustment)	
Sodium hydroxide (pH adjustment)	
Water for injections	

Pharmaceutical form

Solution for Injection.

Clear colorless to slightly yellow solution.

Clinical particulars

Target species

Cattle, pigs and sheep

Indications for use, specifying the target species

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 group must be established before the product is used.

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 group must be established before the product is used. The product should only be used if pigs are expected to develop the disease within 2–3 days.

Sheep

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

Contraindications

Do not use in cases of hypersensitivity to macrolide antibiotics or to any of the excipients.

Special warnings for each target species

Cross resistance occurs with other macrolides. Do not administer simultaneously with antimicrobials with a similar mode of action such as other macrolides or lincosamides.

Sheep

The efficacy of antimicrobial treatment of foot rot might be reduced by others 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.

Special precautions for use

Special precautions for use in animals

Use of the 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 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, lincosamides and group B streptogramins, 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 resulting in e.g. reddening of the skin (erythema) and/or dermatitis. 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.

If there is suspicion of a hypersensitivity reaction following accidental exposure (recognised by e.g. itching, difficulty in breathing, hives, swelling on the face, nausea, vomiting) appropriate treatment should be administered. Seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

Adverse reactions (frequency and seriousness)

Target species: Cattle

Very common (>1 animal / 10 animals treated):	Injection site swelling1 Injection site fibrosis1 Injection site haem odema 1 Injection site reaction2 Injection site pain3

1 Can persist for approximately 30 days after injection.

2 Reversible changes of congestion.

3 Transient.

Target species: Pigs

Very common (>1 animal / 10 animals treated):	Injection site reaction1 Injection site fibrosis1 Injection s oedema1 .

1 Can persist for approximately 30 days after injection.

2 Reversible changes of congestion.

Target species: Sheep

Very common (>1 animal / 10 animals treated):

1 Transient, resolving within a few minutes: head shaking, rubbing injection site, backing away.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Use during pregnancy, lactation or lay

Pregnancy and lactation:

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.

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

Interaction with other medicinal products and other forms of interaction

None Known.

Amounts to be administered and administration route

Cattle

Subcutaneous use.

A single subcutaneous injection of 2.5 mg tulathromycin/kg bodyweight (equivalent to 1 ml/40 kg bodyweight). For treatment of cattle over 300 kg bodyweight, divide the dose so that no more than 7.5 ml are injected at one site.

Pigs

Intramuscular use.

A single intramuscular injection of 2.5 mg tulathromycin/kg bodyweight (equivalent to 1 ml/40 kg bodyweight) in the neck.

For treatment of pigs over 80 kg bodyweight, divide the dose so that no more than 2 ml are injected at one site.

For any respiratory disease, it is recommended to treat animals in the early stages of the disease and to evaluate the response to treatment within 48 hours after injection. If clinical signs of respiratory disease persist or increase, or if relapse occurs, treatment should be changed, using another antibiotic, and continued until clinical signs have resolved.

Sheep

Intramuscular use.

A single intramuscular injection of 2.5 mg tulathromycin/kg body weight (equivalent to 1 ml/40 kg body weight) in the neck.

To ensure correct dosage bodyweight should be determined as accurately as possible to avoid underdosing. For multiple vial entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper. The stopper of 50ml and 100ml vials may be safely punctured up to 52 times. The stopper of 250ml, 500ml, and 1000ml vials may be safely punctured up to 80 times.

Overdose (symptoms, emergency procedures, antidotes), if necessary

In cattle at dosages of three, five or ten 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 three or five 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 three or five 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.

Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

Withdrawal period(s)

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.

Pharmacological particulars

Pharmacotherapeutic group: Antibacterials for systemic use, macrolides.

ATCvet code: QJ01FA94.

Pharmacodynamic properties

Tulathromycin is a semi-synthetic macrolide antimicrobial agent, which originates from a fermentation product. It differs from many other macrolides in that it has a long duration of action that is, in part, due to its three amine groups; therefore it has been given the chemical subclass designation of triamilide.

Macrolides are bacteriostatic acting antibiotics and inhibit essential protein biosynthesis by virtue of their selective binding to bacterial ribosomal RNA. They act by stimulating the dissociation of peptidyl-tRNA from the ribosome during the translocation process.

Tulathromycin possesses in vitro activity against *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni* and *Mycoplasma bovis*, and *Actinobacillus pleuropneumoniae, Pasteurella multocida, Mycoplasma hyopneumonia, Haemophilus parasuis* and *Bordetella bronchiseptica* the bacterial pathogens most commonly associated with bovine and swine respiratory disease,

respectively. Increased minimum inhibitory concentration (MIC) values have been found in some isolates of *Histophilus somni* and *Actinobacillus pleuropneumoniae*. In vitro activity against *Dichelobacter nodosus (vir)*, the bacterial pathogen most commonly associated with infectious pododermatitis (foot rot) in sheep has been demonstrated.

Tulathromycin also possesses in vitro activity against *Moraxella bovis*, the bacterial pathogen most commonly associated with infectious bovine keratoconjunctivitis (IBK).

The Clinical and Laboratory Standards Institute CLSI has set the clinical breakpoints for tulathromycin against M. haemolytica, P. multocida, and H. somni of bovine respiratory origin and P. multocida and B. bronchiseptica of swine respiratory origin as ≤16 µg/ml susceptible and ≥64 µg/ml resistant. For A. pleuropneumoniae of swine respiratory origin the susceptible breakpoint is set at ≤64 µg/ml. CLSI has also published clinical breakpoints for tulathromycin based on a disk diffusion method (CLSI document VET08, 4th ed, 2018). No clinical breakpoints are available for H. parasuis. Neither EUCAST nor CLSI have developed standard methods for testing antibacterial agents against veterinary Mycoplasma species and thus no interpretative criteria have been set. Resistance to macrolides can develop by mutations in genes encoding ribosomal RNA (rRNA) or some ribosomal proteins; by enzymatic modification (methylation) of the 23S rRNA target site, generally giving rise to cross-resistance with lincosamides and group B streptogramins (MLSB resistance); by enzymatic inactivation; or by macrolide efflux. MLSB resistance may be constitutive or inducible. Resistance may be chromosomal or plasmid-encoded and may be transferable if associated with transposons, plasmids, integrative and conjugative elements. Additionally, the genomic plasticity of Mycoplasma is enhanced by the horizontal transfer of large chromosomal fragments.

In addition to its antimicrobial properties, tulathromycin demonstrates immune-modulating and antiinflammatory actions in experimental studies. In both bovine and porcine polymorphonuclear cells (PMNs; neutrophils), tulathromycin promotes apoptosis (programmed cell death) and the clearance of apoptotic cells by macrophages. It lowers the production of the pro-inflammatory mediators leukotriene B4 and CXCL-8 and induces the production of anti-inflammatory and pro-resolving lipid lipoxin A4.

Pharmacokinetic particulars

In cattle, the pharmacokinetic profile of tulathromycin when administered as a single subcutaneous dose of 2.5 mg/kg bodyweight, was characterised by rapid and extensive absorption followed by high distribution and slow elimination. The maximum concentration (Cmax) in plasma was approximately 0.5 µg/ml; this was achieved approximately 30 minutes post-dosing (Tmax). Tulathromycin concentrations in lung homogenate were considerably higher than those in plasma. There is strong evidence of substantial accumulation of tulathromycin in neutrophils and alveolar macrophages. However, the *in vivo* concentration of tulathromycin at the infection site of the lung is not known. Peak concentrations were followed by a slow decline in systemic exposure with an apparent elimination half-life (t1/2) of 90 hours in plasma. Plasma protein binding was low, approximately 40%.

The volume of distribution at steady-state (Vss) determined after intravenous administration was 11 l/kg. The bioavailability of tulathromycin after subcutaneous administration in cattle was approximately 90%.

In pigs, the pharmacokinetic profile of tulathromycin when administered as a single intramuscular dose of 2.5 mg/kg bodyweight, was also characterised by rapid and extensive absorption followed by high distribution and slow elimination. The maximum concentration (Cmax) in plasma was approximately 0.6 µg/ml; this was achieved approximately 30 minutes post-dosing (Tmax). Tulathromycin concentrations in lung homogenate were considerably higher than those in plasma. There is strong evidence of substantial accumulation of tulathromycin in neutrophils and alveolar macrophages. However, the *in vivo* concentration of tulathromycin at the infection site of the lung is not known. Peak concentrations were followed by a slow decline in systemic exposure with an apparent elimination half-life (t1/2) of approximately 91 hours in plasma. Plasma protein binding was low, approximately 40%. The volume of distribution at steady-state (Vss) determined after intravenous administration was 13.2 l/kg. The bioavailability of tulathromycin after intramuscular administration in pigs was approximately 88%.

In sheep, the pharmacokinetic profile of tulathromycin, when administered as a single intramuscular dose of 2.5 mg/kg bodyweight, achieved a maximum plasma concentration (Cmax) of 1.19 µg/ml in approximately 15 minutes (Tmax) post-dosing and had an elimination half-life (t1/2) of 69.7 hours. Plasma protein binding was approximately 60-75%. Following intravenous dosing the volume of distribution at steady-state (Vss) was 31.7 l/kg. The bioavailability of tulathromycin after intramuscular administration in sheep was 100%.

Pharmaceutical particulars

Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months

Shelf life after first opening the immediate packaging: 28 days.

Special precautions for storage

Glass vials: This veterinary medicinal product does not require any special storage conditions.

HDPE vials: Do not store above 30°C.

Nature and composition of immediate packaging

Type I clear glass vials or High Density Polyethylene (HDPE) plastic septum crimp vials closed with Type I bromobutyl rubber stoppers and sealed with aluminium seals.

Pack sizes:

•Cardboard box containing 1 vial of 50 ml

•Cardboard box containing 1 vial of 100 ml

•Cardboard box containing 1 vial of 250 ml

•Cardboard box containing 1 vial of 500 ml

•Cardboard box containing 1 vial of 1 L.

The 1L vials are only available in HDPE.

The 500 ml and 1L vials must not be used for pigs or sheep.

Not all pack sizes may be marketed.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Marketing Authorisation Holder (if different from distributor)

(UK only) Norbrook Laboratories Limited, Station Works, Camlough Road, Newry, Co. Down, BT35 6JP, Northern Ireland

(Rest of EU) Norbrook Laboratories (Ireland) Ltd, Rossmore Industrial Estate, Monaghan, Ireland

Marketing Authorisation Number

Vm 02000/4441

Significant changes

Date of the first authorisation or date of renewal

16 April 2020

Date of revision of the text

April 2025.

Any other information

Nil.

Legal category

Legal category:POM-V

GTIN

NOAH Compendium

GTIN description: Tulieve Solution for Injection - 50ml

GTIN:05023534034131

GTIN description: Tulieve Solution for Injection - 100ml

GTIN:05023534034148