Tulieve®

Withdrawal periods

Cattle (meat and offal):
22 days

Pigs (meat and offal):
13 days

Sheep (meat and offal):
16 days

Presentations

50ml and 100ml plastic vials

Tulieve® 100mg/ml solution for injection for cattle, pigs and sheep

PRESENTATION:

Tulieve 100mg/ml solution for injection is a clear colourless to slightly yellow solution. Each 1ml dose contains 100mg Tulathromycin (active), 19.2mg Citric Acid (E330) and 5mg Monothioglycerol (excipients).

USES:

In 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.

In 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.

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

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.

DOSAGE AND ADMINISTRATION:

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

Pigs: A single intramuscular injection of 2.5mg tulathromycin/kg bodyweight (equivalent to 1ml/40kg bodyweight) in the neck. For treatment of pigs over 80kg bodyweight, divide the dose so that no more than 2ml 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: A single intramuscular injection of 2.5mg tulathromycin/kg bodyweight (equivalent to 1ml/40kg body weight) in the neck. To ensure correct dosage bodyweight should be determined as accurately as possible to avoid underdosing.

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.

CONTRAINDICATIONS AND WARNINGS:

Do not use in cases of hypersensitivity to macrolide antibiotics or to any of the excipients. Do not use simultaneously with other macrolides or lincosamides.

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.

OPERATOR WARNINGS:

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. This product may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to tulathromycin should avoid contact with the product. Wash hands after use. Accidental self-injection may cause pain reactions and local swellings which can persist for several days. Take care to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

PHARMACEUTICAL PRECAUTIONS:

Shelf life as packaged for sale: 24 months.
Shelf life after first opening: 28 days.

Do not store above 30°C.

LEGAL CATEGORY:

UK: POM-V

PACKAGE QUANTITY:

High Density Polyethylene (HDPE) plastic septum crimp vials closed with Type I bromobutyl rubber stoppers and sealed with aluminium seals.
Pack sizes available: 50ml and 100ml.

DISPOSAL:

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

MARKETING AUTHORISATION NUMBER:

UK: Vm 02000/4441

MANUFACTURED AND DISTRIBUTED IN NI BY:

Norbrook Laboratories Limited, Newry, Co. Down, BT35 6JP Northern Ireland.

DISTRIBUTED IN GB BY:

Norbrook Laboratories (G.B.) Limited, 1 Saxon Way East, Corby, Northamptonshire, England, NN18 9EY.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.
FOR ANIMAL TREATMENT ONLY.

Norbrook®
www.norbrook.com

USE MEDICINES RESPONSIBLY.
For further details on this product including the dosage regimens, side effects, precautions, warnings and contraindications please see the summary of product characteristics (SPC) available at www.vmd.defra.gov.uk/ProductInformationDatabase/search | Advice on the use of this product should be sought from the medicine prescriber. | 5467-LA(C/S/P)-v1c-UK-05/10/21

NEW

Tulieve®

HARD HITTING
ONE SHOT TREATMENT

TULIEVE® is a new **tulathromycin** injection from Norbrook® - a potent and effective antibiotic treatment supporting efficient swine, beef and sheep production.

Norbrook®

NEW

Tulieve®

HARD HITTING ONE SHOT **BRD** TREATMENT

Tulathromycin:

- Is a semi-synthetic macrolide, differing from many other macrolides in that it has a **long duration of action** that is, in part, due to its three amine groups[1].
- Like other macrolides, the principal mechanism of action against bacteria involves **direct inhibition of essential protein biosynthesis** by selective binding to bacterial 50S ribosomal subunits[2].
- Especially useful in **treatment and metaphylaxis** of bovine respiratory disease (BRD) and swine respiratory disease (SRD)[2].

- Animals treated with **tulathromycin** showed **lower incidence** of BRD, **lower morbidity**, **lower percentage of chronic illness** and **lower mortality** than animals treated with tilmicosin and tildipirosin[3].
- Licensed treatment against *Mycoplasma bovis*[2].
- S/C injection in cattle.
- Same dose rate as Loxicom® LA (1ml/40kg).
- Plastic bottle.

TULIEVE® is a new **tulathromycin** injection from Norbrook® - a potent and effective antibiotic treatment for **BRD, SRD** and early foot rot in sheep.

(1) Summary of product characteristics - Tulieve

(2) SUMMARY REPORT (2), TULATHROMYCIN, COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS, EMEA/MRL/894/04-Final, 2004

(3) Comparison of tulathromycin, tildipirosin, and tilmicosin for control of bovine respiratory disease in steers purchased from auction markets and fed in a Texas feedlot, Kynan L. Sturgess, DVM; David G. Renter, DVM, PhD, THE BOVINE PRACTITIONER-VOL. 51, NO. 1, 2017

Summary of product characteristics - Zactran, https://www.vmd.defra.gov.uk/ProductInformationDatabase/files/SPC_Documents/SPC_2043797.PDF

Summary of product characteristics - Zuprevo, https://www.ema.europa.eu/en/medicines/veterinary/EPAR/zuprevo

Tulieve® **is a 100 mg/ml solution for injection for cattle, pigs and sheep indicated for:**

Cattle

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

Pigs

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

Sheep

- **Treatment of the early stages of infectious pododermatitis (foot rot)**
  - Dichelobacter nodosus

Regarding other treatment options for **BRD** in cattle

- **Tulieve®** has the shortest withdrawal period compared with other actives such as gamithromycin, florfenicol, tylosin and tidipirosin.
- **Tulieve®** has an IBK indication over other actives based on gamithromycin, florfenicol, tylosin and tildipirosin.