TULAVEN

The only tulathromycin in CLAS® vials

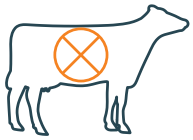
TULAVEN®

PART OF THE CEVA BRD TREATMENT RANGE

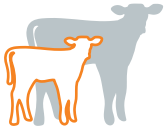
BOVINE RESPIRATORY DISEASE (BRD)
LONG-TERM IMPACT ON CALVES

BRD is a multifactorial disease which has significant impact on the productivity of young dairy and beef calves. The average daily liveweight gain of beef calves with BRD could be reduced by as much as 0.2 kg per day.[1]

Bacteria such as *M. haemolytica, P. multocida, H. somni* and *M. bovis* play a critical role in the pathogenesis of the disease, so the treatment of these bacteria with antibiotics, such as tulathromycin, can significantly improve the health of calves with BRD or those in close contact with infected animals.



Increased mortality



Slower growth rates

Initial treatment costs of up to £65 per dairy heifer calf[2]

PINK EYE

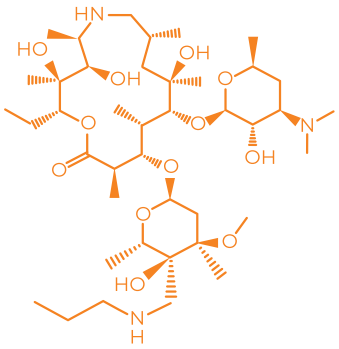
Pink eye, the most common ocular disease of cattle, is caused by the bacterium, *Moraxella bovis.*
A **single dose** of tulathromycin administered subcutaneously, was found to be **an effective treatment.**[3]

OVINE FOOT ROT

Ovine foot rot is a major cause of lameness, affecting the welfare of sheep. The main transmissible pathogen is the bacterium *Dichelobacter nodosus*. In a multicentre field trial, **a single dose** of tulathromycin **successfully treated** early stage foot rot in sheep.[4]

TULAVEN®
FOR THE MANAGEMENT OF BRD

Tulaven® contains tulathromycin, an efficient and trusted antibiotic for the treatment and metaphylaxis of BRD.[5,6] It is characterized by intensive lung distribution, slow elimination, a dual mechanism of action involving inhibition of protein synthesis at the ribosome level and anti-inflammatory properties.



For optimum results when treating BRD, antibiotics can be combined with a Non-Steroidal Anti-inflammatory drug (NSAID) such as meloxicam, to reduce pyrexia and inflammation, prevent significant lung consolidation and help maintain growth rates and calf welfare.

Tulaven® persists above the MIC in tissues, enabling:[7,8]

- **15 days** of coverage for *P. multocida*
- **15 days** of coverage for *H. somni*
- **9 days** of coverage for *M. haemolytica*

Tulaven® is highly syringeable with a convenient low dose volume and and requires only a single subcutaneous administration in cattle

TULAVEN®

PART OF CEVA'S BRD TREATMENT RANGE

Ceva's BRD expertise includes a comprehensive range of products and services to help vets treat this commonly occurring condition.

THE ANTIBIOTIC RANGE

Zeleris®

A first line combination treatment containing florfenicol and meloxicam in a single injection. Highly syringeable[9] and in CLAS® vials.

Florkem®

A highly syringeable[10] florfenicol for injection in CLAS vials.

Tulaven®

A tulathromycin for injection in CLAS vials.

Vetrimoxin® L.A.

A highly syringeable[11], easily resuspended[12] amoxicillin in CLAS vials for use when amoxicillin is the most appropriate antibiotic for a specific farm.

THE NON-STEROIDAL RANGE

Meloxidyl®

Meloxicam for injection. Meloxidyl® can be used alongside an appropriate antibiotic to reduce the pyrexia and inflammation associated with acute BRD. Reducing clinical signs not only improves calf welfare but also limits lung consolidation and helps to maintain feeding and daily liveweight gain.

Allevinix®

Flunixin for injection in CLAS vials (from early 2021). Allevinix® can be given both IV and IM and can be used, alongside appropriate antibiotic therapy, where intravenous NSAIDs are required in cattle with BRD.

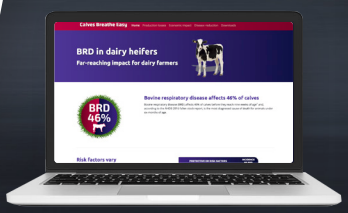
AUTOGENOUS VACCINES

RIDGEWAY BIOLOGICALS

Ridgeway Biologicals is Ceva's autogenous vaccine research, development and manufacturing company. Autogenous vaccines are prepared from a farm-specific pathogen extracted from a host animal or group which is then used to inoculate the rest of the group, and can be used if no commercial vaccine is licensed for the specific pathogen in that animal type.

Ceva has developed a number of support and information tools to help you educate farmers as to the best way to manage and treat BRD.

Bulletins



Website

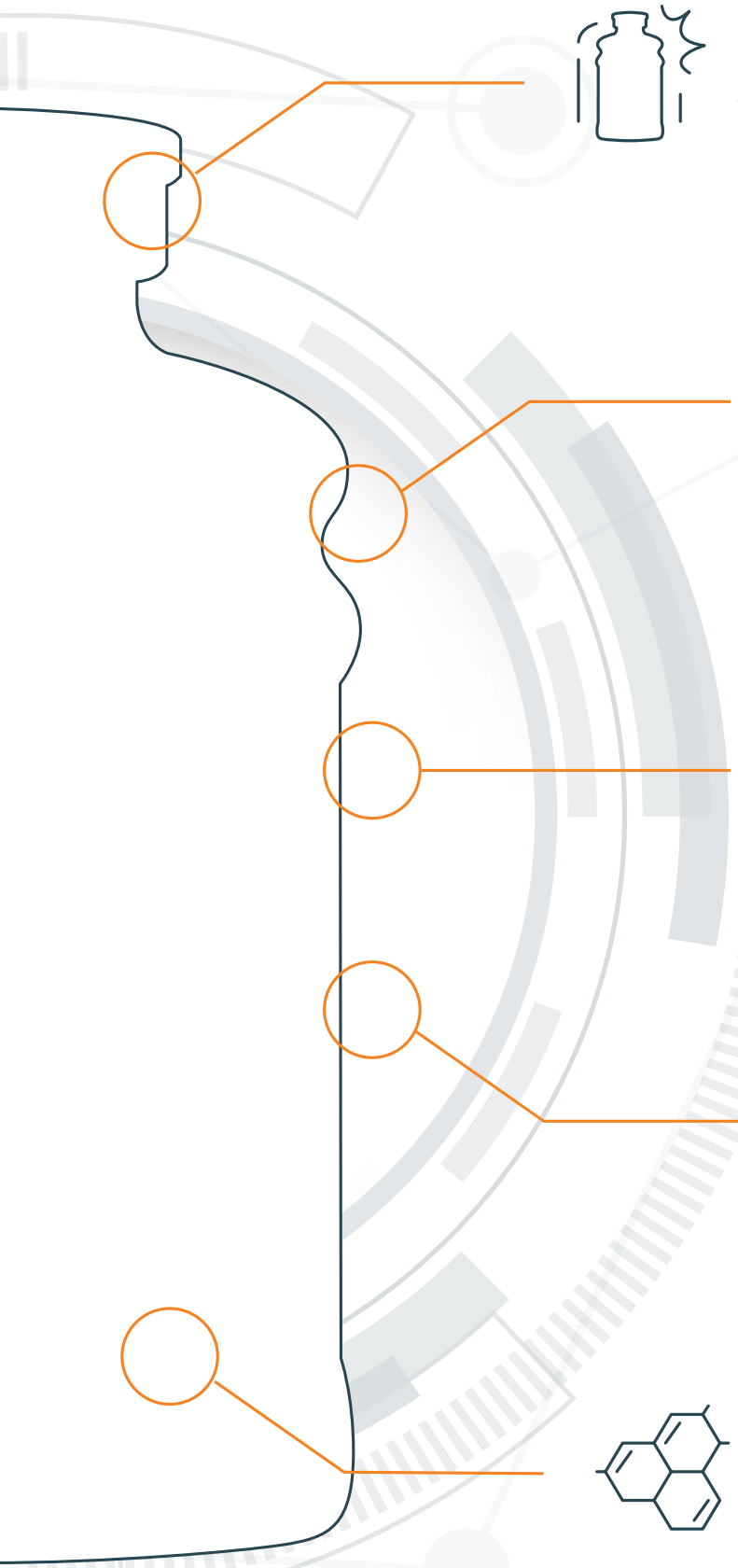
Information

For information about any of the Ceva BRD treatment range or support items please contact your territory manager or call Ceva Animal Health on 0628 334056.

INNOVATIVE
CLAS VIALS

Hi-tech CLAS® vials protect the contents, enhance usability and are eco-friendly.

Most of the Ceva BRD treatment range is now in CLAS VIALS



Shock resistance
for less breakage
and fewer losses[13]

Ergonomic
“grip groove”
for easier
handling[14]

Eco-friendly for
33% less impact on
the environment[15]

Lightweight
material
for easier
transportation
and handling[16]

Hi-tech multi-
layered structure
for product stability[17]

Untreated animals

Waste of **money**

Waste of **injectable**

Waste of **time**

Risk of **injury** and **contamination**

100%

glass vials broke

CLAS VIALS
PROVEN SHOCK RESISTANCE

Shock resistance protocol:

A drop test was performed by Sercovam, an independent company, to assess the resistance to breakage under a 120cm vertical free fall of filled glass vial to CLAS vial, i standardised quality conditions (NF-EN-ISO-2248).[13]

0%

CLAS vials broke

CLAS® **vials** reduce the risk of breakage, waste and untreated animals, and **improve human and animal safety.**

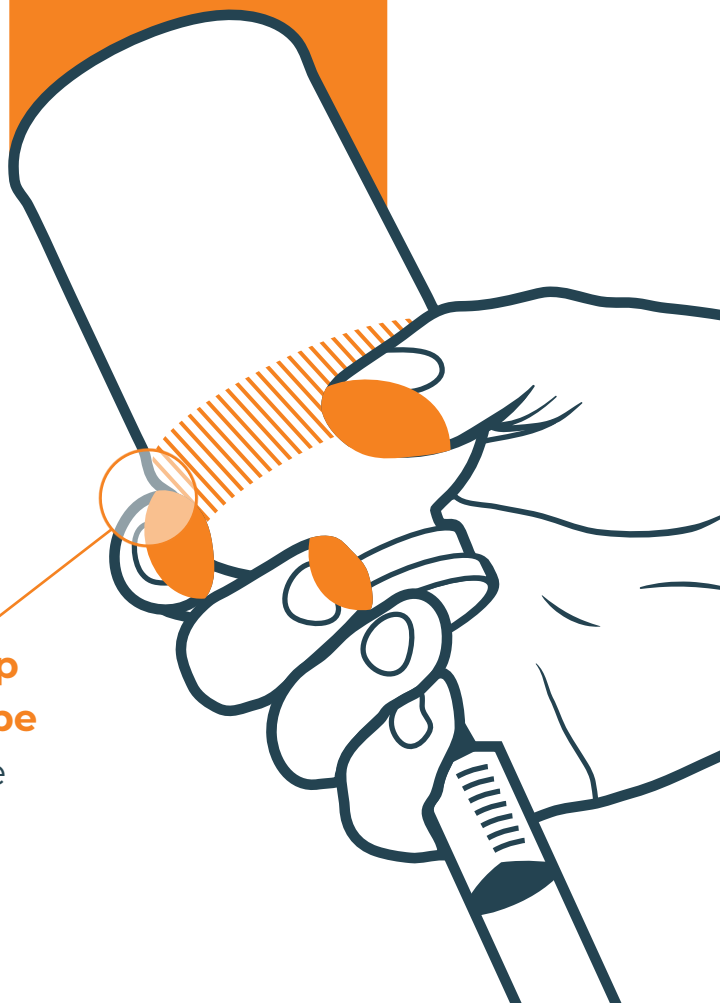
CLAS VIALS
FOR EASIER HANDLING

Ceva commissioned an ergonomic study looking at how users held vials and the results led to the **unique design** of CLAS® vials.[14]

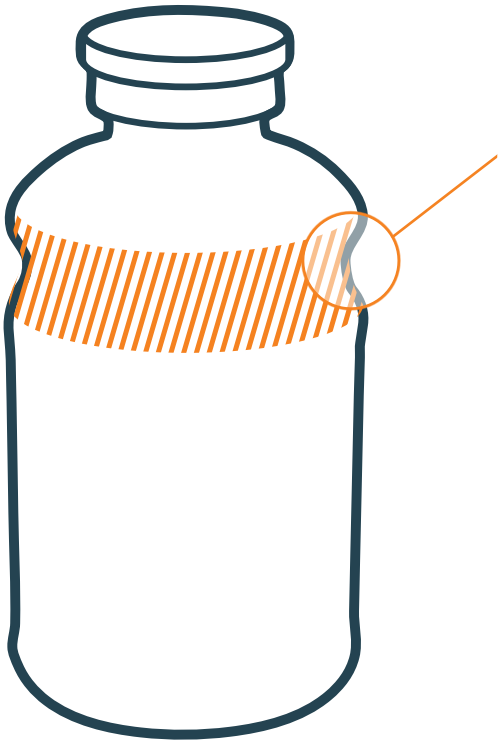
Conclusion:

- ‘Hand Zones’ used to hold the vial were the same for all users
- The shape of standard vials could be improved with **ergonomic holding zones**

CLAS vials
6 times lighter
than glass[16]



VIALS ADAPTED BASED ON THE STUDY RESULTS:



Unique **grip groove shape** to improve handzone holding

- ✓ Easier handling
- ✓ Better grip
- ✓ Less risk of injury

CLAS VIALS
PROVEN TO BE MORE ECO-FRIENDLY

A complete Life Cycle Analysis (LCA) has been conduced by an independant laboratory to compare the environmental impacts of glass and CLAS® vials. Another external critical reviewer has validated the compliance of the LCA with the requirements of ISO 14040 standards (rigorous methodology, reliability of the environmental impacts evaluation...).[15]

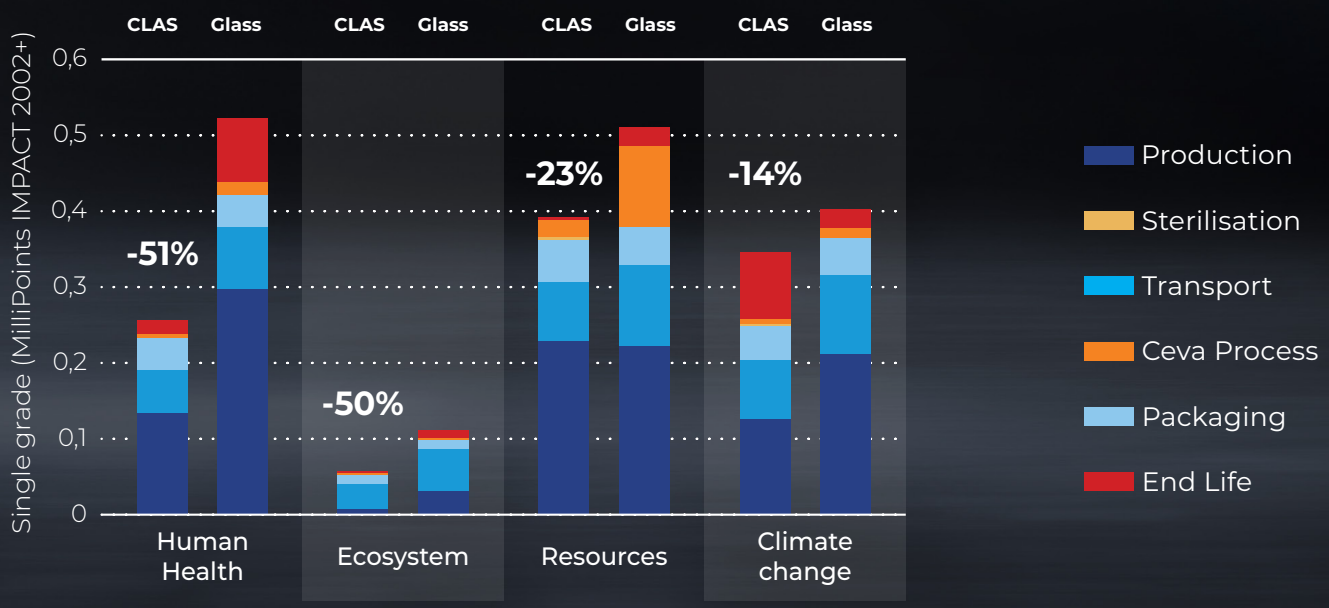
ALL THE PHASES IN THE LIFE CYCLE OF A VIAL WERE CONSIDERED:

15 impact categories were **standardised** and **weighted** to bring them back to a **common unit**. These impact categories were assessed in each of the areas on which they can have consequences (**human health**, **ecosystems**, **resources** and **climate change**).

These impact categories include:

- Toxic or carcinogenic for humans
- Ecotoxicity
- Depletion of fossil-fuel resources
- Global warming
- Freshwater eutrophisation by phosphates
- Fine particle emission
- Acidification (nitrous oxide, sulphur oxide)
- Water depletion

ENVIRONMENTAL IMPACTS: SENSITIVITY ANALYSIS (Impact 2002+)[15]



Taking all production steps into account, **the overall impact on the environment was found to be**

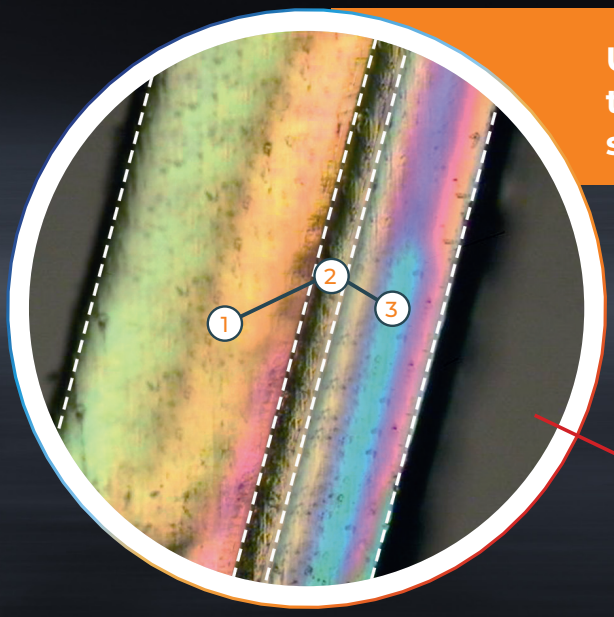
33%

LESS FOR CLAS VIALS

CLAS VIALS
A UNIQUE STRUCTURE

CLAS® VIALS ENSURE THE STABILITY OF TULATHROMYCIN

The hi-tech triple layers make the vial's wall impervious to water and oxygen, yet compatible with organic solvents and sterilisation, leading to product protection and stability.[17]



Unique triple layer structure

CLAS VIALS
PREFERRED BY USERS

Users particularly liked that CLAS vials were **shock resistant**, **lightweight** and had an **ergonomic shape**.[18]

99%

of users preferred the CLAS vial to a glass bottle[18]

TULAVEN

- Only Tulathromycin in **CLAS**® vials
- **Long duration** of action
- **Broad coverage** of BRD pathogens including *Mycoplasma bovis*
- **Single** injection
- **Low dose** volume
- **High safety** profile
- **Highly** effective
- **Short** meat withdrawal **(22 days in cattle)**
- **Excellent** syringeability
- Licensed for use in **cattle**, **swine** and **sheep**

References: 1. Bartram *et al* (2017). Estimating the Lifetime Total Economic Costs of Respiratory Disease in Beef and Dairy Calves In The UK. Value in Health 20 A399-A811 • **2.** van der Fels-Klerx, H.J., Sørensen, J.T., Jalvingh, A.W., Huirne, R.B., 2001. An economic model to calculate farm-specific losses due to bovine respiratory disease in dairy heifers. Prev. Vet. Med. 51, 75–94. • **3.** Lane, V.M., George, L.W., Cleaver, D.M., 2006. Efficacy of tulathromycin for treatment of cattle with acute ocular Moraxella bovis infections. Journal of the American Veterinary Medical Association 229, 557–561. • **4.** CVMP final assessment report for DRAXXIN to add sheep as target species for the 100 mg/ml strength (not for the 500 ml vial) (EMEA/V/C/000077/X/0029) • **5.** O'Connor, A.M., Yuan, C., Cullen, J.N., Coetzee, J.F., da Silva, N., Wang, C., 2016. A mixed treatment meta-analysis of antibiotic treatment options for bovine respiratory disease – An update. Preventive Veterinary Medicine 132, 130–139. • **6.** O'Connor, A.M., Hu, D., Totton, S.C., Scott, N., Winder, C.B., Wang, B., Wang, C., Glanville, J., Wood, H., White, B., Larson, R., Waldner, C., Sargeant, J.M., 2019. A systematic review and network meta-analysis of injectable antibiotic options for the control of bovine respiratory disease in the first 45 days post arrival at the feedlot. Anim Health Res Rev 20, 163–181. • **7.** Nowakowski, M.A., Inskeep, P.B., Risk, J.E., Skogerboe, T.L., Benchaoui, H.A., Meinert, T.R., Sherington, J., Sunderland, S.J., 2004. Pharmacokinetics and lung tissue concentrations of tulathromycin, a new triamilide antibiotic, in cattle. Vet. Ther. 5, 60–74. • **8.** Godinho, K.S., Keane, S.G., Nanjiani, I.A., Benchaoui, H.A., Sunderland, S.J., Jones, M.A., Weatherley, A.J., Gootz, T.D., Rowan, T.G., 2005. Minimum inhibitory concentrations of tulathromycin against respiratory bacterial pathogens isolated from clinical cases in European cattle and swine and variability arising from changes in in vitro methodology. Vet. Ther. 6, 113–121. • **9.** D. Achard, S. Lacoste, M. Letertre, S. Trotebas. Comparison of the syringeability of a new fixed combination of florfenicol and meloxicam (Zeleris®) with florfenicol-based products commonly used in bovine respiratory disease (BRD). • **10.** Manteca C, Lacoste S, Riboud C, Remmy D (2011) Comparison of injectability of 4 different formulations of florfenicol. European Buiatrics Forum, Marseille. 189. • **11.** Lacoste (2011) Study Report Ceva Sante Animal Health. GAL-SLA-C581.0-11030-N. • **12.** Krejci R., Forget P., Guerra N., Lopez A. Resuspendability and syringeability of Vetrimoxin LA in comparison with other injectable amoxicillin products. Proceedings of the apvs 2013 (Vietnam). • **13.** Cavaroc P. J. *et al.* – Comparative breakage study of injectable anti-infectives vials under vertical drop test by free fall under standardized conditions. IPVS Congress, 2012, 100 • **14.** CLAS vials reference book (2012). Section 5.2: Artis Factis and Ceva developed hand zone ergonomic study (2003). P 16 • **15.** Jacquet C. *et al.* Comparative life cycle analysis, final report with critical review, CLAS packaging system and traditional glass packaging system. 2016, APESA 0393 Impact 2002 fig 18 p33, fig.21 p36 • **16.** CLAS vials reference book (2012). Section 5.4: Comparison of the weight of CLAS vials vs. glass vials showing that CLAS vials are 6 X lighter than glass vials of the same size. P19 • **17.** CLAS vials reference book (2012). Section 5.1: R&D challenge: how to create a plastic vial as secure as a glass vial? P14 – 15 • **18.** Lacoste (2011) Study Report Ceva Sante Animal Health. GAL-SLA-C581.0-11030-N. Usage survey conducted on 540 farmers in France.

L423-1120-1.55

Tulaven® 100 mg/ml solution for injection for cattle, pigs and sheep. **Qualitative and quantitave composition**: Each ml contains: Active substance: Tulathromycin: 100 mg. **Indications**: **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. **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 ofthe excipients. Do not use simultaneously with other macrolides or lincosamides. **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). **Pigs**: Intramuscular use, a single intramuscular injection of 2.5 mg tulathromycin/kg bodyweight (equivalent to 1 ml/40 kg bodyweight) in the neck. **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. **Withdrawal periods**: Cattle (meat and offal): 22 days. Pigs (meat and offal): 13 days. Sheep (meat and offal): 16 days. **Legal Category:** UK POM-V IE POM

Tulaven® 25mg/ml solution for injection for pigs contains 25 mg tulathromycin per ml. **Legal Category:** UK POM-V IE POM

Zeleris® 400 mg/ml + 5 mg/ml solution for injection for cattle contains 400 mg florfenicol and 5mg meloxicam per ml. **Legal category**: UK POM-V IE POM

Florkem® 300 mg/ml solution for injection for cattle and pigs contains 300 mg florfenicol per ml. **Legal category**: UK POM-V IE POM

Vetrimoxin® L.A. 150 mg/ml suspension for injection for cattle and pigs contains 150 mg amoxicillin per ml. **Legal category**: UK POM-V IE POM

Meloxidyl® 20 mg/ml solution for injection for cattle, pigs and horses contains 20 mg meloxicam per ml. **Legal category**: UK POM-V IE POM

Allevinix® 50 mg/ml solution for injection for cattle, pigs and horses contains 50 mg flunixin per ml. **Legal category**: UK POM-V

Prescription decisions are for the person issuing the prescription alone. For further information please refer to the product SPC, data sheet or pack insert. Use medicines responsibly (www.noah.co.uk/responsible)

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