TULAVEN

Two concentrations in various volumes :
many options to fit your needs

- In **CLAS** vials
- **Long duration** of action
- Involve **the most important** respiratory pathogens of swine
- **Safe** and **highly** effective
- **Short** withdrawal period **(13 days)**
- **Easy** to administer
- Access to **Ceva Veterinary Services**

Bibliography

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2. Nutsch et al., 2013 - RG Nutsch et al. Efficacy of Draxxin® 25 injectable solution (tulathromycin 25mg/ml) for treatment and control of swine respiratory disease. 2013 Allen D. Leman Swine Conference
3. Villarino et al., 2013 - Villarino N, Lesman S, Fielder A, Garcia-Tapia D, Cox S, Lucas M, et al. (2013). Pulmonary pharmacokinetics of tulathromycin in swine. Part I: lung homogenate in healthy pigs and pigs challenged intratracheally with lipopolysaccharide of Escherichia coli. J. Vet. Pharmacol. Ther. 36329–339. 10.1111/Jvp.12016
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5. Moyaert et al., 2014 - Efficacy of tulathromycin (DRAXXIN 25mg/mL) for the treatment of swine respiratory disease associated with B. bronchiseptica, 23rd IPVS, Cancun, Mexico
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7. Alan B. Scheidt. Duration of effectiveness of tulathromycin (Draxxin® Injectable Solution) in an *Actinobacillus pleuropneumoniae* (serotype 5) challenge model. American Association Of Swine Veterinarians, 2007
8. Klein U, de Jong A, Moyaert H, et al. Antimicrobial susceptibility monitoring of Mycoplasma hyopneumoniae and Mycoplasma bovis isolated in Europe [published correction appears in Vet Microbiol. 2017 Sep;208:173]. Vet Microbiol. 2017;204:188-193.

Tulaven 25 mg/ml solution for injection for pigs. **Qualitative and quantitavie composition**: Each ml contains: Active substance: Tulathromycin 25 mg Excipients: Monothioglycerol 5 mg. **Target species**: 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. **Contraindications**: 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. **Amounts to be administered and administration route**: A single intramuscular injection of 2.5 mg tulathromycin/kg bodyweight (equivalent to 1 ml/10 kg bodyweight) in the neck. For treatment of pigs over 40 kg bodyweight, divide the dose so that no more than 4 ml are injected at one site. **Withdrawal period(s)**: Meat and offal: 13 days. **Pack sizes**: Cardboard box containing 1 plastic vial of 100 ml. Cardboard box containing 1 plastic vial of 250 ml.

cevolution
THE RESPONSIBLE INNOVATION

TULAVEN

First tulathromycin in CLAS vial

ceva

PORCINE RESPIRATORY DISEASE COMPLEX (PRDC): A CRITICAL PROBLEM IN PIG PRODUCTION

Porcine Respiratory Disease Complex is an economically important issue in pig production. A European economic analysis suggests that a single type of respiratory pathogen causing clinical disease in pigs can reduce economic returns of pig production by around **€4.7 per finished pig.**

Several diseases can occur in the herd simultaneously, pushing up total costs **well above these estimates**. On average, *Mycoplasma hyopneumoniae* and Porcine Respiratory Disease Complex (PRDC) reduced the return of investment by €4.2 per pig, and *Actinobacillus pleuropneumoniae* reduced returns by €6.4 per pig in an affected herd[1].

- **High mortality rates**
- **Lower feed efficiency**
- **Welfare issue**
- **Increased time before pigs are ready for market**
- **High treatment costs and increased ATB consumption**

TULAVEN® THE ULTIMATE SOLUTION TO PREVENT, TREAT AND CONTROL PRDC

Tulaven® is an effective solution for the metaphylaxis and treatment of bacterial pathogens involved in PRDC in all production phases (farrowing, nursery and finishing period).

Easy to administrate (one shot): Its concentration dedicated exclusively to swine (25 mg/ml) facilitate optimal administration in farrowing and weaning piglets with only one shot.

- Optimal and Confident administration (peace of mind)
- Reduced financial risk

Safe and high effective: Tulathromycin has unique effect due to its rapid and extensive distribution into the lung tissue (target tissue of respiratory pathogens).[2,3] Very long duration and potential effect can be estimated based on plasma/lung ratio of tulathromycin in lungs. At 408 h (17 days) post-tulathromycin administration, the lung/plasma ratio was >300 for both lung lobes during the Pk/Pd study.[3]

Tulathromycin provides at least 9 days of complete protection against *A. pleuropneumoniae* during the challenge trial.[7] Duration of treatment effect for 15 days was observed based on clinical symptoms and examination of bronchoalveolar lavage (BAL) for *H. parasuis* and *P. multocida*.[4]

Tulathromycin provide 14 days clinical effect for SRD associated with *B. bronchiseptica* based on Day 14 clinical cure rate.[5] Treatment effect of tulathromycin for minimally 13 days was established following experimental infection of swine with *Mycoplasma hyopneumoniae*. Due to the very low and stable MIC_{90} for *M. hyo* strains and Tulathromycin relatively high concentration in lungs we can assume even longer effect. [3,6,8]

Respiratory pathogens	Duration of expected effect
A. pleuropneumoniae	**9 days**
M. hyopneumoniae	**≥ 13 days**
H. parasuis	**15 days**
P. multocida	**15 days**
B. bronchiseptica	**14 days**

THE INNOVATIVE AND HIGH TECH CLAS VIAL

Born from Ceva Research & Development department
The CLAS Hi-tech vial protects the tulathromycin that is used in farm condition.

Robust shock resistant
for less breakage and losses

Ergonomic “grip groove”
for easier handling

Eco-friendly for 33% less impact in the environment

Lightweight material
for easier transportation and handling

Hi-tech multi-layered structure
for great product stability

Untreated animals

Waste of **money**

Waste of **injectable**

Waste of **time**

Mess cleaned up

Risk of **injury**

Contamination
of the ground

100%
broken
glass vial

PROVEN ROBUST SHOCK RESISTANT CLAS VIAL

Shock resistance protocol:

A drop test were 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 standardized quality conditions (NF-EN-ISO-2248).

100%
resistance
for CLAS Vials

By reducing the risk of breakage and injury, **CLAS vials increase animal and human safety in many ways.**

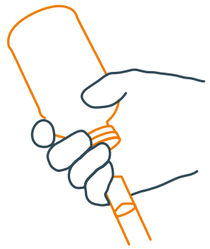
CAVAROC P. J. et al. – Comparative breakage study of injectable anti-infectives vials under vertical drop test by free fall under standardized conditions. IPVS Congress, 2012, 100

An ergonomic study commissioned by Ceva into precise hand zones to hold vials, informed the unique design of its CLAS vial **to maximize ergonomic performance in farm conditions.***

Conclusion:

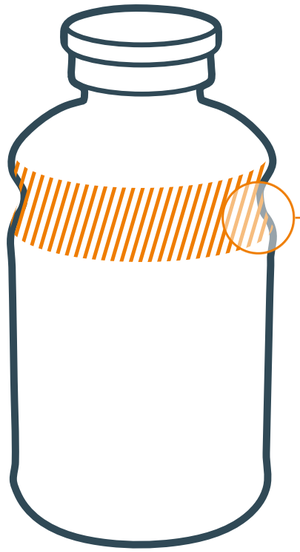
- Hand zone to hold vial during syringe aspiration are the same for all the users
- The shape of the vial can be changed to improve the vial holding

* Internal data

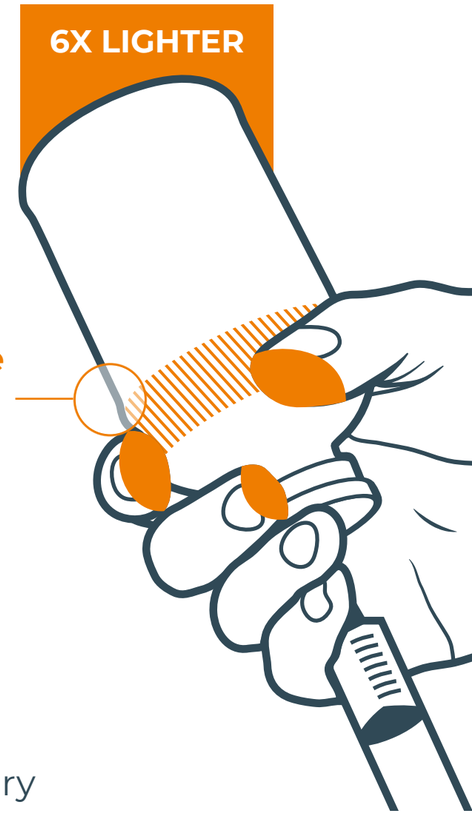


EASIER HANDLING CLAS VIAL

- Improved **ergonomic shape**
- Lighter vial **6 times ligther** compared to glass



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



- ✓ Easier handling
- ✓ Better grip
- ✓ Less risk of injury
- ✓ Less accidental drops and breakage

PROVEN 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...)

The study compared the **overall impact of packagings from craddle to grave.** When comparing CLAS and glass vials, the life cycle analysis took into account **all the phases in the life of a vial:**

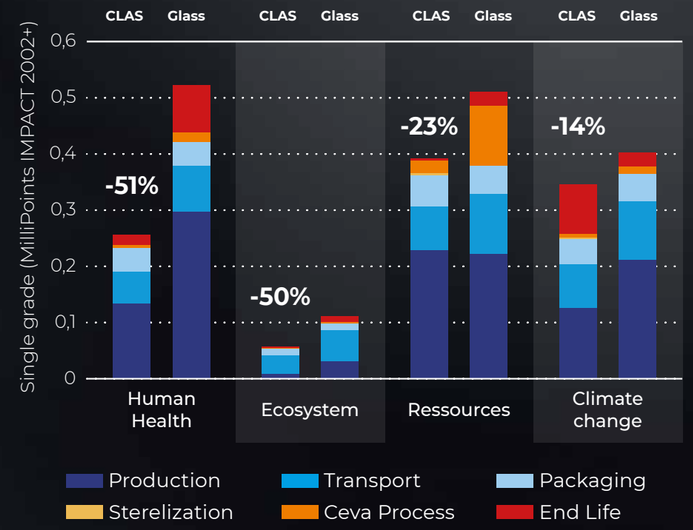
Impact 2000+

There are **15 impact categories**, which are **standardized** and **weighted** to bring them back to a **common unit**. These impacts are also cumulated in each of the protection areas on which they can have consequences (**human health**, **ecosystems**, **resources** and **climate change**).

This 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, sulfur oxide)
- Water depletion

ENVIRONMENTAL IMPACTS: SENSITIVITY ANALYSIS (Impact 2002+)



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

33% LESS FOR CLAS VIALS.

Jacquet C. et al. Analyse de cycle de vie comparative, rapport final avec revue critique, système de conditionnement CLAS et Système de conditionnement traditionnel en verre. 2016, APESA 0393 impact 2002+ fig18 p33, fig21 p36.

UNIQUE STRUCTURE

CLAS VIALS ALLOW A GREAT STABILITY OF TULATHROMYCIN

The hi-tech triple layers make the vial's wall impervious to water and oxygen, and compatible with organic solvents and sterilisation.

The hi-tech triple layers insures the clas vial **best protection and stability of tulathromycin**

CLAS VIALS
PREFERED BY USERS

Thanks to its **lightweight** and **shock resistance, ergonomic shape,** CLAS is prefered by users

"99%

prefer the CLAS bottle to the glass bottle for its impact resistance in 90% of case "

*Study carried out in 2012 by Ceva France among 540 farmers