

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box (50 ml / 100 ml / 250 ml)}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Tullavis 25 mg/ml solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Tulathromycin                      25 mg/ml

**3. PACKAGE SIZE**

50 ml  
100 ml  
250 ml

**4. TARGET SPECIES**

Pigs

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Intramuscular use.

**7. WITHDRAWAL PERIODS**

Withdrawal periods:  
Meat and offal: 13 days.

**8. EXPIRY DATE**

Exp. {mm/yyyy}  
Once broached use within 28 days.  
Once broached use by:

**9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 30 °C.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Industrial Veterinaria SA

**14. MARKETING AUTHORISATION NUMBERS**

Vm 36547/5004

Vm 36547/3004

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**  
**{VIAL (100 ML /250 ML)}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Tullavis 25 mg/ml solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Tulathromycin                      25 mg/ml

**3. TARGET SPECIES**

Pigs

**4. ROUTES OF ADMINISTRATION**

**i.m.**

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal periods:  
Meat and offal: 13 days.

**6. EXPIRY DATE**

Exp. {mm/yyyy}  
Once broached use within 28 days.  
Once broached use by:

**7. SPECIAL STORAGE PRECAUTIONS**

Do not store above 30 °C.

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Industrial Veterinaria SA

**9. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE  
PACKAGING UNITS {VIAL (50 ML)}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Tullavis  
Pigs

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Tulathromycin          25 mg/ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}  
Once broached use by:

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

Tullavis 25 mg/ml solution for injection for pigs

**2. Composition**

Each ml contains:

**Active substances:**

Tulathromycin            25 mg

**Excipients:**

Monothioglycerol       5 mg

Clear colourless to yellowish solution.

**3. Target species**

Pigs.

**4. Indications for use**

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 veterinary medicinal product should only be used if pigs are expected to develop the disease within 2–3 days.

**5. Contraindications**

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

**6. Special warnings**

Special warnings:

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

Special precautions for safe use in the target species:

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 package leaflet 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. 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.

Pregnancy and lactation:

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.

Overdose:

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.

Major incompatibilities:

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

**7. Adverse events**

Pigs:

Very common (>1 animal / 10 animals treated):
Injection site reaction <sup>1,2</sup> , Injection site fibrosis (scarring) <sup>1</sup> , Injection site haemorrhage <sup>1</sup> , Injection site oedema <sup>1</sup>

<sup>1</sup> Can persist for approximately 30 days after injection.

<sup>2</sup> Reversible changes of congestion.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system at <https://www.gov.uk/report-veterinary-medicine-problem>.

## **8. Dosage for each species, routes and method of administration**

Intramuscular use (i.m.).

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.

## **9. Advice on correct administration**

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.

To ensure correct dosage bodyweight should be determined as accurately as possible. The cap may be safely punctured up to 100 times. For multiple vial entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper.

## **10. Withdrawal periods**

Meat and offal: 13 days.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Do not store above 30 °C.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

### **14. Marketing authorisation numbers and pack sizes**

Vm 36547/5004

Vm 36547/3004

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.

Not all pack sizes may be marketed.

### **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

### **16. Contact details**

Marketing authorisation holder:

Industrial Veterinaria SA  
Calle Esmeralda, 19  
08950 Esplugues de Llobregat  
Spain

Manufacturer responsible for batch release:

aniMedica GmbH  
Im Südfeld 9  
48308 Senden-Bösensell  
Germany

aniMedica Herstellungs GmbH  
Im Südfeld 9  
48308 Senden-Bösensell  
Germany

Industrial Veterinaria, S.A.  
Esmeralda, 19  
08950 Esplugues de Llobregat (Barcelona)  
Spain

Local representatives and contact details to report suspected adverse events:

FORTE Healthcare Limited  
Block 3, Unit 9  
CityNorth Business Campus  
Stamullen, Co.  
Meath. K32 D990  
Republic of Ireland  
Tel.: +353 1 841 7666

**17. Other information**

POM-V

Veterinary medicinal product subject to prescription

*Gavin Hall*  
Approved: 19 November 2025