PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box (20 ml / 50 ml / 100 ml / 250 ml)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tullavis 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Tulathromycin 100 mg/ml

3. PACKAGE SIZE

20 ml
50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle, pigs and sheep

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: subcutaneous use.
Pigs and sheep: intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal:
Cattle: 22 days.
Pigs: 13 days.
Sheep: 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

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 36547/5003
Vm 36547/3003

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 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Tulathromycin 100 mg/ml

3. TARGET SPECIES

Cattle, pigs and sheep

4. ROUTES OF ADMINISTRATION

Cattle: **s.c.**
Pigs and sheep: **i.m.**

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal:
Cattle: 22 days.
Pigs: 13 days.
Sheep: 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

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 (20 ML / 50 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tullavis
Cattle, pigs, sheep

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

2. Composition

Each ml contains:

Active substances:
Tulathromycin 100 mg

Excipients:
Monothioglycerol 5 mg

Clear colourless to yellowish solution.

3. Target species

Cattle, pigs and sheep.

4. Indications for use

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 veterinary medicinal 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.

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.

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.

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 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 five to six 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.

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

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):
Injection site swelling[1], Injection site fibrosis (scarring)[1], Injection site haemorrhage[1], Injection site oedema[1], Injection site reaction[1,2], Injection site pain[3]

[1] Can persist for approximately 30 days after injection.
[2] Reversible changes of congestion.
[3] Transient.

Pigs:

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

[1] Can persist for approximately 30 days after injection.
[2] Reversible changes of congestion.

Sheep:

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

[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. 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

Cattle: subcutaneous use (**s.c.**)
Pigs and sheep: intramuscular use (**i.m.**)

Cattle:
2.5 mg tulathromycin/kg bodyweight (equivalent to 1 ml/40 kg bodyweight).

A single subcutaneous injection. 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:
2.5 mg tulathromycin/kg bodyweight (equivalent to 1 ml/40 kg bodyweight).

A single intramuscular injection 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.

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

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

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.

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 36547/5003
Vm 36547/3003

Pack sizes:
Cardboard box containing one vial of 20 ml.
Cardboard box containing one vial of 50 ml.
Cardboard box containing one vial of 100 ml.
Cardboard box containing one 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.

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

Approved 06 October 2026
Gavin Hall