

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

REXXOLIDE 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Tulathromycin 100 mg

3. PACKAGE SIZE

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

Meat and offal:
Cattle: 22 days.
Pigs: 13 days.
Sheep: 16 days.

Not authorised for use in lactating 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.

9. SPECIAL STORAGE PRECAUTIONS

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

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBER

Vm 50406/5052

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE { Vial (glass - 100 ml / 250 ml)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

REXXOLIDE 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Tulathromycin 100 mg

3. TARGET SPECIES

Cattle, pigs and sheep.



4. ROUTES OF ADMINISTRATION

Cattle: Subcutaneous use.
Pigs and sheep: Intramuscular use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Meat and offal:
Cattle: 22 days.
Pigs: 13 days.
Sheep: 16 days.

Not authorised for use in lactating 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.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS { Vial (glass - 50 ml)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

REXXOLIDE



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 within 28 days.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:

Tulathromycin 100 mg

Excipients:

Monothioglycerol 5 mg

Clear colourless to slightly yellow solution for injection.

3. Target species

Cattle, pigs and sheep.

4. Indications for use

Cattle:

Treatment and metaphylaxis of bovine respiratory disease 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 veterinary medicinal product is used.

Treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis* susceptible to tulathromycin.

Pigs:

Treatment and metaphylaxis of swine respiratory disease 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 veterinary medicinal 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 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 product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies. Use of the veterinary medicinal product deviating from the instructions given in the SPC 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 resulting in e.g. reddening of the skin (erythema) and/or dermatitis. 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.

If there is suspicion of a hypersensitivity reaction following accidental exposure (recognised by e.g. itching, difficulty in breathing, hives, swelling on the face, nausea, vomiting) appropriate treatment should be administered. Seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

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 pain ^a , injection site swelling ^a Injection site reactions (e.g. injection site congestion, injection site oedema, injection site fibrosis, injection site haemorrhage) ^b
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^aTransient, can persist for up to 30 days.

^bPathomorphological reversible changes, for approximately 30 days after injection.

Pigs:

Very common (>1 animal / 10 animals treated):	Injection site reactions (e.g. injection site congestion, injection site oedema, injection site fibrosis, injection site haemorrhage) ^a
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^aPathomorphological reversible changes, for approximately 30 days after injection.

Sheep:

Very common (>1 animal / 10 animals treated):	Discomfort ^a Head shake ^a , backing away ^a Injection site scratching ^a
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^aThese signs resolve within a few minutes.

Reporting adverse events is important. It allows continuous safety monitoring of a 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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Cattle:

Subcutaneous use.

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:

Intramuscular use.

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:

Intramuscular use.

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 a correct dosage, body weight should be determined as accurately as possible.

For multiple vial entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper. The stopper may be safely punctured up to 25 times.

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 lactating 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.

This veterinary medicinal product does not require any special storage conditions.
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.
Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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 50406/5052

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.

16. Contact details

Marketing authorisation holder:

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM- VPS
POM-V
AVM- GSL
NFA- VPS

Gavin Hall

Approved: 09 July 2025