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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZACTRAN 150 mg/ml solution for injection for cattle, sheep and pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per 1 ml:
gamithromycin 150 mg

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle, sheep and pigs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

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

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: Cattle: 64 days. Sheep: 29 days. Pigs: 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 (cows, heifers) or 1 month (ewes) of expected parturition.

8. EXPIRY DATE

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

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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBER

Vm 04491/5061

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V (‘Veterinary medicinal product subject to prescription’)

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box (500 ml)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZACTRAN 150 mg/ml solution for injection for cattle and pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per 1 ml:
gamithromycin 150 mg

3. PACKAGE SIZE

500 ml

4. TARGET SPECIES

Cattle, pigs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Cattle: Subcutaneous use.
Pigs: Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: Cattle: 64 days. Pigs: 16 days.
Not authorised for use in animals producing milk for human consumption.
Do not use in pregnant cows and heifers 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

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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBER

Vm 04491/5061

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V (‘Veterinary medicinal product subject to prescription’)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Glass vial 50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZACTRAN

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

50 ml

Per 1 ml:
gamithromycin 150 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

5. ROUTE(S) OF ADMINISTRATION

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {VIAL 100 ml, 250 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZACTRAN 150 mg/ml solution for injection for cattle, sheep and pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per 1 ml:
gamithromycin 150 mg

100 ml
250 ml

3. TARGET SPECIES

Cattle, sheep and pigs

4. ROUTES OF ADMINISTRATION

SC (cattle, sheep) IM (pigs)
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: Cattle: 64 days. Sheep: 29 days. Pigs: 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 (cows, heifers) or 1 month (ewes) of expected parturition.

6. EXPIRY DATE

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

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V (‘Veterinary medicinal product subject to prescription’)

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {VIAL 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZACTRAN 150 mg/ml solution for injection for cattle and pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per 1 ml:
gamithromycin 150 mg

500 ml

3. TARGET SPECIES

Cattle, pigs

4. ROUTES OF ADMINISTRATION

SC (cattle) IM (pigs)
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: Cattle: 64 days. Pigs: 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 (cows, heifers) of expected parturition.

6. EXPIRY DATE

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

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V (‘Veterinary medicinal product subject to prescription’)

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZACTRAN 150 mg/ml solution for injection for cattle, sheep and pigs

2. COMPOSITION

Each ml contains
Active substance: 150 mg of gamithromycin
Excipients: 1 mg of monothioglycerol

Colourless to pale yellow solution.

3. TARGET SPECIES

Cattle, sheep and pigs.

4. INDICATIONS FOR USE

Cattle:
Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with *Histophilus somni, Mannheimia haemolytica* and *Pasteurella multocida*.
The presence of the disease in the group should be established before the product is used.

Pigs:
Treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae Bordetella bronchiseptica, Glaesserella parasuis and Pasteurella multocida.*

Sheep:
Treatment of infectious pododermatitis (foot rot) associated with virulent *Dichelobacter nodosus* and *Fusobacterium necrophorum* requiring systemic treatment.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of the excipients or to other macrolide antibiotics.
Do not use this veterinary medicinal product simultaneously with other macrolides or lincosamides.

6. SPECIAL WARNINGS

Special warnings:
Cattle, pigs and sheep:
Cross resistance has been shown between gamithromycin and other macrolides.
Use of the product should be carefully considered when susceptibility testing has shown resistance to other macrolides because its effectiveness may be reduced
Avoid simultaneous administration of 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.

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.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to the macrolide class should avoid contact with the veterinary medicinal product. Gamithromycin may cause irritation to eyes and/or skin.
Avoid contact with skin or eyes. If eye exposure occurs, flush eyes immediately with clean water. If skin exposure occurs, wash the affected area immediately with clean water.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in cattle, sheep and pigs.
Based on laboratory animal data, gamithromycin has not produced any evidence of specific developmental or reproductive effects. Use according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
See “special warnings”

Overdose:
Clinical studies have demonstrated the wide margin of safety for gamithromycin injection in the target species. In young adult cattle, sheep and pig studies, gamithromycin was administered by injection at 6, 18, and 30 mg/kg (1, 3, and 5 times the recommended dose) and repeated three times at 0, 5 and 10 days (three times the recommended duration of use). Injection site reactions were noted in a dose related manner.

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 pain[2].

[1] Typically resolves within 3 to 14 days but may persist for up to 35 days
[2] Slight pain may develop for 1 day

Sheep:

Common (1 to 10 animals / 100 animals treated): injection site swelling[3], injection site pain[4].

[3] Mild to moderate and typically resolves within 4 days
[4] Slight pain may develop for 1 day

Pigs:

Common (1 to 10 animals / 100 animals treated): injection site swelling.[5]

[5] Mild to moderate and typically resolves within 2 days

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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

A single dose of 6 mg gamithromycin/kg body weight (equivalent to 1 ml/25 kg body weight) into the neck (cattle and pigs) or anterior to the shoulder (sheep).

Cattle and sheep: **subcutaneous** injection. For treatment of cattle over 250 kg and sheep over 125 kg body weight, divide the dose so that no more than 10 ml (cattle) and 5 ml (sheep) are injected at a single site.

Pigs: **intramuscular** injection. The injection volume should not exceed 5 ml per injection site.

This multi-usage presentation requires an automatic dosing device to be used to avoid excessive broaching of the stopper.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure correct dose, body weight should be determined as accurately as possible.

10. WITHDRAWAL PERIODS

Meat and offal: Cattle: 64 days. Sheep: 29 days. Pigs: 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 (cows, heifers) or 1 month (ewes) 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 vial 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.

Dispose of waste material in accordance with local requirements. These measures should help to protect the environment.

Ask your veterinary surgeon 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 04491/5061

Type 1 glass vial of 50, 100, 250 or 500 ml with a chlorobutyl rubber stopper, a polypropylene cap and an aluminium crimp seal or only an aluminium crimp seal.

Polypropylene vial of 100, 250 or 500 ml with a chlorobutyl rubber stopper, a polypropylene cap and an aluminium crimp seal.

Cardboard box containing 1 vial of 50, 100, 250 or 500 ml.

The 500 ml vial is for cattle and pigs only.

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 and contact details to report suspected adverse reactions:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4, Chemin du Calquet
31000 Toulouse
France

Local representatives and contact details to report suspected adverse events:
United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Limited
Tel: + 44 1344 746957

17. OTHER INFORMATION

For animal treatment only POM-V ('Veterinary medicinal product subject to prescription')

Approved 04 September 2024
Gavin Hall