PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton – 100 ml, 250 ml, or 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gamrozyne 150 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Gamithromycin 150 mg/ml

3. PACKAGE SIZE

100 ml
250 ml
500 ml

4. TARGET SPECIES

Cattle, Sheep, Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle and Sheep: Subcutaneous injection.
Pigs: Intramuscular injection.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle:
Meat and offal: 64 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.

Sheep:
Meat and offal: 29 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 1 month of expected parturition.

Pigs:
Meat and offal: 16 days.

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Store below 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

Bimeda Animal Health Limited.

14. MARKETING AUTHORISATION NUMBERS

GB - Vm 50146/5006
NI – Vm 50146/3005

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Vial – 100 ml, 250 ml, or 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gamrozyne 150 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Gamithromycin 150 mg/ml

3. TARGET SPECIES

Cattle, Sheep, Pigs.

4. ROUTES OF ADMINISTRATION

Cattle and Sheep: Subcutaneous injection.
Pigs: Intramuscular injection.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
Meat and offal: 64 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.

Sheep:
Meat and offal: 29 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 1 month of expected parturition.

Pigs:
Meat and offal: 16 days.

6. EXPIRY DATE

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

7. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Gamrozyne 150 mg/ml Solution for Injection for Cattle, Sheep and Pigs

2. Composition

Each ml contains:

Active substance:
Gamithromycin 150 mg

Excipients:
Monothioglycerol 1 mg

Colourless to pale yellow solution.

3. Target species

Cattle
Sheep
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 cases 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 macrolides or lincosamides. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to macrolides or lincosamides 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.
Not for use for prophylaxis.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause hypersensitivity reactions.
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 veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy: Based on laboratory animal data, gamithromycin has not produced any evidence of specific developmental or reproductive effects. Use only 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.

Special restrictions for use and special conditions for use:
Not applicable.

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 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 https://www.gov.uk/report-veterinary-medicine-problem.

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) or 5 ml (sheep) are injected at a single site.

Pigs:
Intramuscular injection.
The injection volume should not exceed 5 ml per injection site.
The cap may be safely punctured up to 30 times with a 18G needle. In the event of using a 16G needle or for multiple vial entry, an automatic dosing device shall 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

Cattle:
Meat and offal: 64 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.

Sheep:
Meat and offal: 29 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 1 month of expected parturition.

Pigs:
Meat and offal: 16 days.

11. Special storage precautions

Store below 30 °C.
Keep out of the sight and reach of children.
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.
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

GB - Vm 50146/5006
NI – Vm 50146/3005

Type 1 glass vial of 100, 250 or 500 ml with a chlorobutyl rubber stopper and an aluminium seal.
Cardboard box containing 1 vial of 100, 250 or 500 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 (UK GB)

Marketing authorisation holder and manufacturer responsible for batch release:
Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

Local representative and contact details to report suspected adverse reactions:
Cross Vetpharm Group UK Limited (Trading as Bimeda)
Unit 2, Bryn Cefni Industrial Park
Llangefni, LL77 7XA
United Kingdom
Tel: 01248 725 400

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

16. Contact details (UK NI)

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght, Dublin 24, Ireland,
Tel.: +353 01 466 7900

17. Other information

POM-V

Gavin Hall

Approved: 02 October 2024