ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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
gamithromycin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 150 mg of gamithromycin,

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, sheep, pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP
Shelf life after first opening the container: 28 days
Once opened, use by __/__/__

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/5061

17. MANUFACTURER'S BATCH NUMBER

Lot

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
gamithromycin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 150 mg of gamithromycin,

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Cattle, pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal: Cattle: 64 days. Pigs: 16 days.
Not authorised for use in lactating 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.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP
Shelf life after first opening the container: 28 days
Once opened, use by __/__/__

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/5061

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE UNITS

VIAL 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains 150 mg of gamithromycin

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

SC (cattle, sheep), IM (pigs)

5. WITHDRAWAL PERIOD(S)

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.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP
Once opened, use by __/__/__

8. 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
gamithromycin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 150 mg of gamithromycin,

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle, sheep, pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: Cattle: 64 days. Sheep: 29 days. Pigs: 16 days.
Not authorised for use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP
Once opened, use by __/__/__

11. SPECIAL STORAGE CONDITIONS

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/5061

17. MANUFACTURER'S BATCH NUMBER

Lot

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
gamithromycin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 150 mg of gamithromycin,

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Cattle, pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: Cattle: 64 days. Pigs: 16 days.
Not authorised for use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP
Once opened, use by __/__/__

11. SPECIAL STORAGE CONDITIONS

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/5061

17. MANUFACTURER'S BATCH NUMBER

Lot

B. PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

1 ml contains
Active substance: 150 mg of gamithromycin
Excipients: 1 mg of monothioglycerol
Colourless to pale yellow solution.

4. INDICATION(S)

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

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

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 a certain type of antibiotics called macrolides or to any of the excipients.
Do not use this veterinary medicinal product simultaneously with other macrolides or antibiotics known as lincosamides.

6. ADVERSE REACTIONS

During clinical trials transient injection site swellings were observed.

- Visible injection site swellings associated with occasional slight pain may develop very commonly in cattle for one day. The swellings typically resolve within 3 to 14 days but may persist in some animals for up to 35 days after treatment.
- Mild to moderate injection site swelling has been reported commonly, in sheep and pigs in clinical trials, with occasional pain evident for one day in sheep. These local reactions are transient and typically resolve within 2 (pigs) to 4 (sheep) days.

The frequency of adverse reactions is defined using the following convention:

- Very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- Common (more than 1 but less than 10 animals in 100 animals treated)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- Rare (more than 1 but less than 10 animals in 10,000 animals treated)
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, sheep and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

The cap may be safely punctured up to 50 times with a 16G needle and up to 80 times with a 18G needle. For multiple vial entry, an automatic dosing device is recommended 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 to avoid underdosing.
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.

10. WITHDRAWAL PERIOD(S)

Meat and offal: Cattle: 64 days. Sheep: 29 days. Pigs: 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 (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.
Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Use of the veterinary medicinal product should be based on susceptibility testing and take into account official and local policies on the use of antimicrobials in farm animals.

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 gamithromycin during pregnancy and lactation has not been evaluated in cattle, sheep and pigs. Use according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Cross resistance may occur with other macrolides.
Avoid simultaneous administration of antimicrobials with a similar mode of action such as other macrolides or lincosamides.

Overdose:
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.

Incompatibilities:
Do not mix with other medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

Approved: 01 March 2021