ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Gamithromycin 150 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Monothioglycerol	1 mg
Succinic Acid	
Glycerol Formal	

Colourless to pale yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep and pigs.

3.2 Indications for use for each target species

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.

3.3 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 (see section 3.8).

3.4 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.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the 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.

3.8 Interaction with other medicinal products and other forms of interaction

See section 3.4

3.9 Administration routes and dosage

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

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.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.
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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC vet code: QJ01FA95

4.2 Pharmacodynamics

Gamithromycin is an azalide, 15-membered semisynthetic macrolide class antibiotic with uniquely positioned alkylated nitrogen at 7a-position of the lactone ring. This special chemistry facilitates rapid absorption at physiological pH and a long duration of action at the target tissues, the lung and the skin. Macrolides in general have both bacteriostatic and bactericidal action mediated through disruption of bacterial protein synthesis. Macrolides inhibit bacterial protein biosynthesis by binding to the 50S ribosomal subunit and by preventing peptide chain elongation. The *in vitro* data show that gamithromycin acts in a bactericidal manner. The broad spectrum antimicrobial activity of gamithromycin includes *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni*, *Actinobacillus pleuropneumoniae, Glaesserella parasuis and Bordetella bronchiseptica,* the bacterial pathogens most commonly associated with BRD and SRD, and also *Fusobacterium necrophorum* and *Dichelobacter nodosus*. The MIC and MBC data (cattle and pig) are reported from a representative sample of isolates from field materials within different EU geographic areas.

Cattle	MIC_{90s}	MBC_{90s}
	µg/ml	
Mannheimia haemolytica	0.5	1
Pasteurella multocida	1	2
Histophilus somni	1	2
Pigs	MIC_{90s}	MBC_{90s}
	µg/ml	
Actinobacillus pleuropneumoniae	4	4
Pasteurella multocida	1	2
Glaesserella parasuis	0.5	0.5
Bordetella bronchiseptica	2	4
Sheep	MIC	
	µg/ml	
Fusobacterium necrophorum	MIC_{90}: 32	
Dichelobacter nodosus	0.008 – 0.016	

Three mechanisms are generally considered responsible for resistance to the macrolide class of compounds. This is often referred to as MLS_B resistance as it affects macrolides, lincosamides and streptogramins. The mechanisms involve the alteration of the ribosomal target site, the utilization of active efflux mechanism and the production of inactivating enzymes.

4.3 Pharmacokinetics

Cattle
Gamithromycin administered subcutaneously into the neck of cattle at a single dose of 6 mg/kg body weight, resulted in rapid absorption with peak plasma concentrations observed after 30 to 60 min with a long plasma half-life (> 2 days). The bioavailability of the compound was > 98% with no gender differences. The volume of distribution at steady-state was 25 l/kg. Gamithromycin levels in lung reached a maximum in less than 24 hr, with lung-to-plasma ratio of > 264 indicating that gamithromycin was absorbed rapidly into the target tissue for BRD.

In vitro plasma protein binding studies determined that the mean concentration of the free active substance was 74%. Biliary excretion of the unchanged drug substance was the major route of elimination.

Pigs
Gamithromycin administered intramuscularly in pigs at single dose of 6 mg/kg body weight, resulted in rapid absorption with peak plasma concentrations observed after 5 to 15 min, with a long plasma half-life (about **4** days). The bioavailability of gamithromycin was > 92%. The compound is absorbed rapidly into the target tissue for SRD. Accumulation of gamithromycin in the lung has been demonstrated by high and sustained concentrations in the lung and bronchial fluid which far exceed those in blood plasma. The volume of distribution at steady-state was approximately 39 l/kg. *In vitro* plasma protein binding studies determined that the mean concentration of the free active drug was 77%. Biliary excretion of the unchanged drug was the major route of elimination.

Sheep
Gamithromycin administered subcutaneously into the neck of sheep at a single dose of 6 mg/kg body weight is rapidly absorbed, and maximum plasma concentrations were observed between 15 minutes and 6 hours after dosing (2.30 hours on average) with high absolute bioavailability of 89%.

Gamithromycin skin concentrations were much higher than the plasma concentrations resulting in skin/plasma concentration ratios of approximately 21, 58, and 138 at two, five and ten days post-dosing, respectively, demonstrating extensive distribution and accumulation in skin tissue.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/082/001-007

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 24/07/2008

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

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

2. STATEMENT OF ACTIVE SUBSTANCES

Per 1 ml:
gamithromycin 150 mg

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle, sheep and pigs

5. INDICATIONS

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 NUMBERS

EU/2/08/082/001 Vial (glass) 100 ml
EU/2/08/082/002 Vial (glass) 250 ml
EU/2/08/082/004 Vial (PP) 100 ml
EU/2/08/082/005 Vial (PP) 250 ml
EU/2/08/082/007 Vial (glass) 50 ml

15. BATCH NUMBER

Lot {number}

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 SUBSTANCES

Per 1 ml:
gamithromycin 150 mg

3. PACKAGE SIZE

500 ml

4. TARGET SPECIES

Cattle, pigs

5. INDICATIONS

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 NUMBERS

EU/2/08/082/003 Vial (glass) 500 ml
EU/2/08/082/006 Vial (PP) 500 ml

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE UNITS

GLASS VIAL 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZACTRAN

2. 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:_

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 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 period:
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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

9. BATCH NUMBER

Lot {number}

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 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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

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: {national system details}.

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 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

EU/2/08/082/001-007

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. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

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
or
Fresenius Kabi Austria GmbH
Hafnerstrasse 36
8055 Graz
Austria

Local representatives and contact details to report suspected adverse events:

België/Belgique/Belgien
Boehringer Ingelheim Animal Health Belgium SA
Avenue Arnaud Fraiteurlaan 15-23,
1050 Bruxelles/Brussel/Brüssel
Tél/Tel: + 32 2 773 34 56

Република България
Boehringer Ingelheim RCV GmbH & Co KG
Dr. Boehringer Gasse 5-11
A-1121 Виена
Tel: +359 2 958 79 98

Česká republika
Boehringer Ingelheim spol. s r.o.
Purkyňova 2121/3
CZ - 110 00, Praha 1
Tel: +420 234 655 111

Danmark
Boehringer Ingelheim Animal Health Nordics A/S
Weidekampsgade 14
DK-2300 København S
Tlf: + 45 3915 8888

Deutschland
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Tel: 0800 290 0 270

Eesti
Boehringer Ingelheim RCV GmbH & Co KG
Eesti filiaal
Dr. Boehringer Gasse 5-11
A-1121 Viin
Tel: +372 612 8000

Ελλάδα
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein
Τηλ: +30 2108906300

España
Boehringer Ingelheim Animal Health España, S.A.U.
Prat de la Riba, 50
08174 Sant Cugat del Vallès (Barcelona)
Tel: +34 93 404 51 00

Lietuva
Boehringer Ingelheim RCV GmbH & Co KG
Lietuvos filialas
Dr. Boehringer Gasse 5-11
A-1121 Vīne
Tel: +370 5 2595942

Luxembourg/Luxemburg
Boehringer Ingelheim Animal Health Belgium SA
Avenue Arnaud Fraiteurlaan 15-23,
1050 Bruxelles/Brussel/Brüssel
Tél/Tel: + 32 2 773 34 56

Magyarország
Boehringer Ingelheim RCV GmbH & CoKG
Magyarországi Fióktelep
Dr. Boehringer Gasse 5-11
A-1121 Bécs
Tel: +36 1 299 8900

Malta
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein
Tel: +353 1 291 3985

Nederland
Boehringer Ingelheim Animal Health Netherlands bv
Basisweg 10
1043 AP Amsterdam
Tel: +31 20 799 6950

Norge
Boehringer Ingelheim Animal Health Nordics A/S
Weidekampsgade 14
DK-2300 København S
Tlf: +47 66 85 05 70

Österreich
Boehringer Ingelheim RCV GmbH & Co KG
Dr. Boehringer Gasse 5-11
A-1121 Wien
Tel: +43 1 80105-6880

Polska
Boehringer Ingelheim Sp. z o.o.
ul. Józefa Piusa Dziekonskiego 3
00-728 Warszawa
Tel.: + 48 22 699 0 699

France
Boehringer Ingelheim Animal Health France, SCS
29, avenue Tony Garnier
69007 Lyon
Tél : +33 4 72 72 30 00

Hrvatska
Boehringer Ingelheim RCV GmbH & Co KG
Dr. Boehringer Gasse 5-11
A-1121 Beč
Tel: +385 1 2444 600

Ireland
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein
Tel: +353 1 291 3985

Ísland
Vistor
Hörgatún 2
210 Garðabær
Sími: + 354 535 7000

Italia
Boehringer Ingelheim Animal Health Italia S.p.A.
Via Vezza d'Oglio, 3
20139 Milano
Tel: +39 02 53551

Κύπρος
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein
Τηλ: +30 2108906300

Latvija
Boehringer Ingelheim RCV GmbH & Co KG
Latvijas filiāle
Dr. Boehringer Gasse 5-11
A-1121 Viena
Tel: +371 67 240 011

Portugal
Boehringer Ingelheim Animal Health Portugal, Unipessoal, Lda.
Avenida de Pádua, 11
1800-294 Lisboa
Tel: +351 21 313 5300

România
Boehringer Ingelheim RCV GmbH & Co KG
Sucursala București
Dr. Boehringer Gasse 5-11
A-1121 Viena
Tel: +40 21 302 28 00

Slovenija
Boehringer Ingelheim RCV GmbH & Co KG
Podružnica Ljubljana
Dr. Boehringer Gasse 5-11
A-1121 Dunaj
Tel: +386 1 586 40 00

Slovenská republika
Boehringer Ingelheim RCV GmbH & Co KG, o.z.
Dr. Boehringer Gasse 5-11
A-1121 Viedeň
Tel: +421 2 5810 1211

Suomi/Finland
Vetcare Oy
PL/PB 99
24101 Salo
Puh/Tel: + 358 201443360

Sverige
Boehringer Ingelheim Animal Health Nordics A/S
Weidekampsgade 14
DK-2300 København S
Tlf: +46 (0)40-23 34 00

United Kingdom (Northern Ireland)
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein
Tel: +353 1 291 3985