

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimprocil 300mg/ml suspension for injection for cattle sheep and pigs (AT, BE, DE, ES, IE, IT, NL, PL, PT, UK(NI))

Bimprocil suspension for injection for cattle sheep and pigs (FR)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substances:

Benzylpenicillin procaine 300 mg  
(corresponding to 175.8 mg of benzylpenicillin)

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl parahydroxybenzoate E218	2.0 mg
Povidone K30	
Sodium citrate	
Disodium edetate	
Lecithin	
Potassium dihydrogen phosphate	
Potassium chloride	
Water for injections	

An off-white suspension.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle, sheep and pigs.

### 3.2 Indications for use for each target species

For the treatment of acute systemic infections caused by bacteria susceptible to benzylpenicillin.

### 3.3 Contraindications

Do not inject intravenously.

Do not use in cases of hypersensitivity to penicillin, cephalosporins, procaine or to any of the excipients.

Do not use in cases of severe renal dysfunction with anuria and oliguria.

Do not use in very small herbivores such as guinea pigs, gerbils and hamsters.

Do not use in the presence of  $\beta$ -lactamase producing pathogens.

### 3.4 Special warnings

Complete cross-resistance has been shown between benzylpenicillin procaine and other penicillins.

After absorption, benzylpenicillin poorly penetrates biological membranes (e.g., blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the veterinary medicinal product for treatment of meningitis or CNS infections due to e.g., *Streptococcus suis* or *Listeria monocytogenes* may not be efficacious. Furthermore, benzylpenicillin penetrates mammalian cells poorly and hence this veterinary medicinal product may have little effect in treating intracellular pathogens e.g., *Listeria monocytogenes*.

Elevated MIC values or bi-modal distribution profiles suggesting acquired resistance have been reported for the following bacteria:

- *Glaesserella parasuis*, *Staphylococcus* spp. causing MMA/PPDS, *Streptococcus* spp. and *S. suis* in pigs.

- *Fusobacterium necrophorum* causing metritis and *Mannheimia haemolytica* (only in some member states), as well as *Bacteroides* spp., *Staphylococcus chromogenes*, *Actinobacillus lignieresii* and *Trueperella pyogenes* in cattle.

Use of the veterinary medicinal product may result in a lack of clinical efficacy when treating infections caused by these bacteria.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to benzylpenicillin and may decrease the effectiveness of treatment with other penicillins and cephalosporins due to the potential for cross-resistance.

The feeding of waste milk containing residues of antibiotics to calves should be avoided up to the end of the milk withdrawal period (except during the colostrum phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

#### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Penicillins and cephalosporins may cause sensitisation following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

This veterinary medicinal product also contains a paraben preservative which may cause a contact hypersensitivity reaction in previously sensitised individuals.

Do not handle this product if you know that you are sensitised, or if you have been advised not to work with such preparations. People developing a reaction after contact with the product should avoid handling the product and other penicillin and cephalosporin containing products in the future.

Personal protective equipment consisting of gloves should be worn when handling and administering the veterinary medicinal product.

Handle this product with care to avoid exposure.

In case of accidental contact with eyes, rinse immediately with copious amounts of water. Accidental spillage on the skin should be washed immediately with soap and water.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

If you develop symptoms such as a skin rash following exposure, seek medical advice and show this warning to the doctor. Swelling of the face, lips, eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

### Special precautions for the protection of the environment:

Not applicable.

### **3.6 Adverse events**

Pigs:

Uncommon (1 to 10 animals / 1 000 animals treated):	Pyrexia <sup>1</sup> , Vomiting <sup>1</sup> , Shivering <sup>1</sup> , Listless <sup>1</sup> , Incoordination <sup>1</sup>
Undetermined frequency (cannot be estimated from the available data)	Systemic disorder <sup>2</sup> , Vaginal discharge <sup>3</sup>

<sup>1</sup> In suckling and fattening pigs, transient

<sup>2</sup> Toxic effects have been observed in young piglets. Transient but can be potentially lethal, especially at higher doses

<sup>3</sup> In pregnant sows and gilts, could be associated with abortion

Cattle:

Rare (1 to 10 animals / 10 000 animals treated):	Anaphylactic type reactions <sup>1</sup>
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Allergic reaction <sup>2</sup> , Anaphylactic shock <sup>2</sup>

<sup>1</sup> Due to povidone content

<sup>2</sup> To penicillin, may occasionally be serious

Sheep: None known

In case of side effects, the animal should be treated symptomatically.

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**

#### Pregnancy and lactation:

There is no evidence that this veterinary medicinal product presents any particular hazard to the dam or foetus. However, in pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

Use during pregnancy and lactation only according to the benefit-risk assessment by the responsible veterinarian.

### **3.8 Interaction with other medicinal products and other forms of interaction**

The effect of aminoglycosides can be enhanced by penicillins.

The excretion of benzylpenicillin is prolonged by acetylsalicylic acid. Cholinesterase inhibitors delay the degradation of procaine.

Benzylpenicillin is bactericidal. Avoid concurrent use of bactericidal and bacteriostatic antibiotics as they can antagonise the bactericidal effect of penicillins.

### **3.9 Administration routes and dosage**

Intramuscular use.

Dosage: 12 mg procaine benzylpenicillin (corresponding to 7 mg benzylpenicillin) per kg bodyweight (equivalent to 2 ml of the veterinary medicinal product per 50 kg bw) per day.

The treatment duration is 3 to 7 days.

The appropriate treatment duration should be chosen based on the clinical needs and individual recovery of the treated animal. Consideration should be given to the accessibility of the target tissue and characteristics of the target pathogen.

The maximum volumes to be injected at any one site are 20 ml (Cattle), 3 ml (Pigs) and 2 ml (Sheep).

The vials can only be broached a maximum of 30 times.

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

Before use, shake the vial gently for a minimum of 10 seconds until all sediment is readily dispersed.

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

Tolerance studies have been conducted at twice the recommended dosage rate in all three target species without any ill-effects being observed.

In the case of overdose, central nervous symptoms and/or convulsions may occur.

### **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 periods**

Cattle:

Meat and offal: 10 days for treatment duration 3 days.

12 days for treatment duration 4-7 days.

Milk: 108 hours (4.5 days).

Pigs:

Meat and offal: 7 days for treatment duration 3 days.

9 days for treatment duration 4-7 days.

Sheep:

Meat and offal: 4 days for treatment duration 3 days.

6 days for treatment duration 4-7 days.

Not authorised for use in sheep producing milk for human consumption.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code :**

QJ01CE09

### **4.2 Pharmacodynamics**

Procaine benzylpenicillin is a complex, sparingly soluble organic salt of benzylpenicillin.

Benzylpenicillin exerts its effect on multiplying bacteria by blocking the biosynthesis of the bacterial wall.

Penicillin is a  $\beta$ -lactam antibiotic which has bactericidal activity against mainly Gram-positive bacteria and some Gram-negative organisms susceptible to penicillin.

Enterobacteriales, *Bacteroides fragilis*, most *Campylobacter* spp., *Nocardia* spp. and *Pseudomonas* spp. as well as beta-lactamase-producing *Staphylococcus* spp. are resistant.

Resistance to benzylpenicillin is recognised to occur in some isolates of pathogens for which this veterinary medicinal product is indicated. The most common resistance mechanism is the veterinary medicinal production of  $\beta$ -lactamase enzyme. Resistance may also result from alterations to penicillin binding proteins (PBP).

There is cross-resistance between penicillins and other beta-lactam antibiotics. Where a pathogen has acquired penicillin resistance by the transfer of mobile genetic elements, co-resistance to other antimicrobial classes may also be present.

### **4.3 Pharmacokinetics**

Following intramuscular injection of the veterinary medicinal product, peak concentrations of penicillin in plasma are reached within 1 to 2 hours.

Use of the procaine salt is intended to delay absorption of the drug from the injection site and to give rise to a longer duration of action.

## **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**

Store in a refrigerator (2 °C – 8 °C).

### **5.4 Nature and composition of immediate packaging**

The veterinary medicinal product is packaged in clear 100 ml Type I and 250 ml clear Type III glass vials sealed with red or grey, siliconised bromobutyl rubber stoppers and aluminium overseal, containing a sterile aqueous suspension.

Carton box with 1 vial of 100 ml

Carton box with 1 vial of 250 ml

12 shrink-wrapped boxes containing 1 vial of 100 ml

12 shrink-wrapped boxes containing 1 vial of 250 ml

Carton box with 48 boxes containing 1 vial of 100 ml

Carton box with 48 boxes containing 1 vial of 250 ml

The vials are colourless.

Not all pack sizes may be marketed.

**5.5 Special precautions for the disposal of unused veterinary medicinal products 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 national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Bimeda Animal Health Limited

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: {DD month YYYY}.

**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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton Box (100 ml & 250 ml)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Bimprocil 300mg/ml suspension for injection (AT, BE, DE, ES, IE, IT, NL, PL, PT, UK(NI))  
Bimprocil suspension for injection (FR)

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

Benzylpenicillin procaine 300 mg  
(corresponding to 175.8 mg of benzylpenicillin)

**3. PACKAGE SIZE**

100 ml  
250 ml  
12x100 ml  
12x250 ml  
48x100 ml  
48x250 ml

**4. TARGET SPECIES**

Cattle, sheep and pigs.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Intramuscular use.

**7. WITHDRAWAL PERIODS**

Withdrawal periods:

Cattle:

Meat and offal: 10 days for treatment duration 3 days.  
12 days for treatment duration 4-7 days.

Milk: 108 hours (4.5 days).

Pigs:

Meat and offal: 7 days for treatment duration 3 days.  
9 days for treatment duration 4-7 days.

Sheep:

Meat and offal: 4 days for treatment duration 3 days.  
6 days for treatment duration 4-7 days.

Not authorised for use in sheep producing milk for human consumption.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days.

Once broached, use by: ..../..../....

**9. SPECIAL STORAGE PRECAUTIONS**

Store in a refrigerator (2 °C – 8 °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**

EU/0/00/000/000

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

{100 ml Vial & 250 ml Vial}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Bimprocil 300 mg/ml suspension for injection (AT, BE, DE, ES, IE, IT, NL, PL, PT, UK(NI))  
Bimprocil suspension for injection (FR)

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:  
Benzylpenicillin procaine 300 mg  
(corresponding to 175.8 mg of benzylpenicillin)

**3. TARGET SPECIES**

Cattle, sheep and pigs.

**4. ROUTES OF ADMINISTRATION**

Intramuscular use.

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal periods:

Cattle:

Meat and offal: 10 days for treatment duration 3 days.  
12 days for treatment duration 4-7 days.

Milk: 108 hours (4.5 days).

Pigs:

Meat and offal: 7 days for treatment duration 3 days.  
9 days for treatment duration 4-7 days.

Sheep:

Meat and offal: 4 days for treatment duration 3 days.  
6 days for treatment duration 4-7 days.

Not authorised for use in sheep producing milk for human consumption.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days.

Once broached, use by: .../.../....

**7. SPECIAL STORAGE PRECAUTIONS**

Store in a refrigerator (2 °C – 8 °C).

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Bimeda Animal Health Limited

**9. BATCH NUMBER**

Lot {number}

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Bimprocil 300 mg/ml suspension for injection for cattle sheep and pigs (AT, BE, DE, ES, IE, IT, NL, PL, PT, UK(NI))

Bimprocil suspension for injection for cattle sheep and pigs (FR)

### 2. Composition

Each ml contains:

#### Active substances:

Benzylpenicillin procaine 300 mg  
(corresponding to 175.8 mg benzylpenicillin)

#### Excipients:

Methyl parahydroxybenzoate E218 2.0 mg

An off-white suspension

### 3. Target species

Cattle, sheep and pigs.

### 4. Indications for use

For the treatment of acute systemic infections caused by bacteria susceptible to benzylpenicillin.

### 5. Contraindications

Do not inject intravenously.

Do not use in cases of hypersensitivity to penicillin, cephalosporins, procaine or to any of the excipients.

Do not use in cases of severe renal dysfunction with anuria and oliguria.

Do not use in very small herbivores such as guinea pigs, gerbils and hamsters.

Do not use in the presence of  $\beta$ -lactamase producing pathogens.

### 6. Special warnings

#### Special warnings:

Complete cross-resistance has been shown between benzylpenicillin procaine and other penicillins. After absorption, benzylpenicillin poorly penetrates biological membranes (e.g., blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the veterinary medicinal product for treatment of meningitis or CNS infections due to e.g., *Streptococcus suis* or *Listeria monocytogenes* may not be efficacious. Furthermore, benzylpenicillin penetrates mammalian cells poorly and hence this veterinary medicinal product may have little effect in treating intracellular pathogens e.g., *Listeria monocytogenes*.

Elevated MIC values or bi-modal distribution profiles suggesting acquired resistance have been reported for the following bacteria:

- *Glaesserella parasuis*, *Staphylococcus* spp. causing MMA/PPDS, *Streptococcus* spp. and *S. suis* in pigs;

- *Fusobacterium necrophorum* causing metritis and *Mannheimia haemolytica* (only in some member states), as well as *Bacteroides* spp., *Staphylococcus chromogenes*, *Actinobacillus lignieresii* and *Trueperella pyogenes* in cattle.

Use of the veterinary medicinal product may result in a lack of clinical efficacy when treating infections caused by these bacteria.

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Use of the veterinary medicinal product deviating from the instructions given in the package leaflet may increase the prevalence of bacteria resistant to benzylpenicillin and may decrease the effectiveness of treatment with other penicillins and cephalosporins due to the potential for cross-resistance.

The feeding of waste milk containing residues of antibiotics to calves should be avoided up to the end of the milk withdrawal period (except during the colostrum phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Penicillins and cephalosporins may cause sensitisation following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

This veterinary medicinal product also contains a paraben preservative which may cause a contact hypersensitivity reaction in previously sensitised individuals.

Do not handle this product if you know that you are sensitised, or if you have been advised not to work with such preparations. People developing a reaction after contact with the product should avoid handling the product and other penicillin and cephalosporin containing products in the future.

Personal protective equipment consisting of gloves should be worn when handling and administering the veterinary medicinal product.

Handle this product with care to avoid exposure.

In case of accidental contact with eyes, rinse immediately with copious amounts of water. Accidental spillage on the skin should be washed immediately with soap and water.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

If you develop symptoms such as a skin rash following exposure, seek medical advice and show this warning to the doctor. Swelling of the face, lips, eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Pregnancy and lactation:

There is no evidence that this veterinary medicinal product presents any particular hazard to the dam or foetus. However, in pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

Use during pregnancy and lactation only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

The effect of aminoglycosides can be enhanced by penicillins.

The bactericidal efficacy of penicillin is counteracted by bacteriostatic medicinal products.

The excretion of benzylpenicillin is prolonged by acetylsalicylic acid. Cholinesterase inhibitors delay the degradation of procaine.

Benzylpenicillin is bactericidal. Avoid concurrent use of bactericidal and bacteriostatic antibiotics as they can antagonise the bactericidal effect of penicillins.

Overdose:

Tolerance studies have been conducted at twice the recommended dosage rate in all three target species without any ill-effects being observed.

In the case of overdose, central nervous symptoms and/or convulsions may occur.

**Major incompatibilities:**

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

**7. Adverse events**

Pigs:

Uncommon (1 to 10 animals / 1 000 animals treated):	Pyrexia (fever) <sup>1</sup> , Vomiting <sup>1</sup> , Shivering <sup>1</sup> , Listless <sup>1</sup> , Incoordination <sup>1</sup>
Undetermined frequency (cannot be estimated from the available data)	Systemic disorder <sup>2</sup> , Vaginal discharge <sup>3</sup>

<sup>1</sup> In suckling and fattening pigs, transient

<sup>2</sup> Toxic effects have been observed in young piglets. Transient but can be potentially lethal, especially at higher doses

<sup>3</sup> In pregnant sows and gilts, could be associated with abortion

Cattle:

Rare (1 to 10 animals / 10 000 animals treated):	Anaphylactic type reactions (severe allergic reaction) <sup>1</sup>
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Allergic reaction <sup>2</sup> , Anaphylactic shock <sup>2</sup>

<sup>1</sup> Due to povidone content

<sup>2</sup> To penicillin, may occasionally be serious

Sheep: None known.

In case of side effects, the animal should be treated symptomatically.

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 its local representative 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**

Intramuscular use.

Dosage: 12 mg procaine benzylpenicillin (corresponding to 7 mg benzylpenicillin) per kg bodyweight (equivalent to 2 ml of the veterinary medicinal product per 50 kg bw) per day.

The treatment duration is 3 to 7 days.

The appropriate treatment duration should be chosen based on the clinical needs and individual recovery of the treated animal. Consideration should be given to the accessibility of the target tissue and characteristics of the target pathogen.

The maximum volumes to be injected at any one site are 20 ml (Cattle), 3 ml (Pigs) and 2 ml (Sheep).

The vials can only be broached a maximum of 30 times.  
To ensure a correct dosage body weight should be determined as accurately.  
Before use, shake the vial gently for a minimum of 10 seconds until all sediment is readily dispersed.

#### **9. Advice on correct administration**

See **Dosage for each species, routes and method of administration.**

#### **10. Withdrawal periods**

Cattle:

Meat and offal: 10 days for treatment duration 3 days.  
12 days for treatment duration 4-7 days.

Milk: 108 hours (4.5 days).

Pigs:

Meat and offal: 7 days for treatment duration 3 days.  
9 days for treatment duration 4-7 days.

Sheep:

Meat and offal: 4 days for treatment duration 3 days.  
6 days for treatment duration 4-7 days.

Not authorised for use in sheep producing milk for human consumption.

#### **11. Special storage precautions**

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).

Shelf life after first opening the container: 28 days.

Do not use this veterinary medicinal product after the expiry date which is stated on the vial and carton after “EXP”. The expiry date refers to the last day of that month.

#### **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 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**

1 x 100 ml, 12 x 100 ml, 48 x 100 ml,

1 x 250 ml, 12 x 250 ml, 48 x 250 ml.

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release:

Bimeda Animal Health Limited

2, 3 & 4 Airton Close

Airton Road, Tallaght

Dublin 24

Ireland

Local representatives <and contact details to report suspected adverse events:

**17. Other information**