[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

COBACTAN 2.5% w/v suspension for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
25 mg Cefquinome (as cefquinome sulfate)

Excipients

Qualitative composition of excipients and other constituents
Ethyloleat

Milky-white to slightly brownish suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each target species

For the treatment of bacterial infections in cattle and pigs caused by the Gram-positive and Gram-negative microorganisms sensitive to cefquinome.

Cattle:
Respiratory disease caused by *Pasteurella multocida* and *Mannheimia haemolytica*
Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)
Acute *Escherichia coli* mastitis with signs of systemic involvement

Calves:
Escherichia coli septicaemia in calves

Pigs:
For the treatment of bacterial infections of the lungs and respiratory tract caused by *Pasteurella multocida, Haemophilus parasuis, Actinobacillus pleuropneumoniae, Streptococcus suis* and other cefquinome-sensitive organisms
Mastitis-Metritis-Agalactia syndrome (MMA) with involvement of *Escherichia coli, Staphylococcus* spp*., Streptococcus* spp. and other cefquinome sensitive organisms

Piglets:
Reduction of mortality in cases of meningitis caused by *Streptococcus suis*.
For the treatment of:
Arthritis caused by *Streptococcus ssp., Escherichia coli* and other cefquinome-sensitive organisms.
Epidermitis (mild or moderate lesions) caused by *Staphylococcus hyicus*

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, ß-lactam antibiotics or to any of the excipients. Do not administer to animals less than 1.25 kg body weight.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal product selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) which may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, the veterinary medicinal product should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly (refers to very acute cases when treatment must be initiated without bacteriological diagnosis), to first line treatment. Official, national and regional antimicrobial policies should be taken into account when the product is used. Increased use, including use of the product deviating from the instructions given in the SPC, may increase the prevalence of such resistance. Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.

The veterinary medicinal product is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

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

1. Do not handle this veterinary medicinal product if you know you are sensitized, or if you have been advised not to work with such preparation.
2. Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.
3. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.
4. Cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle and pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction, Injection site lesion[1]

[1] are repaired 15 days after the last administration

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

There is no available information indicating reproductive toxicity in cattle or pigs.

Pregnancy and lactation:

In reproduction toxicity studies in laboratory animals cefquinome did not reveal any effect on reproduction or teratogenic potential. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

It is known that a cross sensitivity to cephalosporin exists for bacteria sensitive to the cephalosporin group.

Due to undesirable pharmacodynamic interaction, do not apply cefquinome simultaneously with pharmaceuticals acting bacteriostatically.

3.9 Administration routes and dosage

Intramuscular use.

Species	Indication	Dosage	Frequency
Cattle	Respiratory disease caused by *Pasteurella multocida* and *Mannheimia haemolytica* Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 3 or 5 consecutive days
	Acute *Escherichia coli* mastitis with signs of systemic involvement	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 2 consecutive days
Calves	*Escherichia coli* septicaemia	2 mg cefquinome/kg bw (4 ml/50 kg bw)	Once daily for 3 or 5 consecutive days
Pigs	Respiratory disease	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 3 consecutive days.
	MMA	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 2 consecutive days.
Piglets	Meningitis Arthritis Epidermitis	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 5 consecutive days

Studies have indicated the advisability of giving second and subsequent injections at a different injection site. The preferred injection site is in muscular tissue in the mid neck.
To ensure a correct dosage, body weight should be determined as accurately as possible.

Shake the vial well before using.
The veterinary medicinal product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry sterile needle and syringe. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes, for example when treating piglets. The cap may be safely punctured up to 25 times. The 50ml vial should be used for treating small piglets. When treating groups of animals, use a draw-off needle.

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

Overdoses of 20 mg/kg/day in cattle and 10 mg/kg/day in pigs and piglets have been well tolerated.

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)*:* 5 days
Cattle (milk)*:* 24 hours
Pig (meat and offal)*:* 3 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01DE90

4.2 Pharmacodynamics

In vitro activity has been demonstrated against common Gram-positive and Gram-negative bacteria including *Escherichia coli*, *Citrobacter* spp., *Klebsiella* spp., *Mannheimia haemolytica*, *Pasteurella multocida*, *Proteus* spp., *Salmonella* spp., *Serratia marcescens*, *Haemophilus somnus*, *Arcanobacterium pyogenes*, *Bacillus* spp., *Corynebacterium* spp., *Staphylococcus* spp., *Streptococcus* spp., *Bacteroides* spp., *Clostridium* spp., *Fusobacterium* spp., *Prevotella* spp., *Actinobacillus* spp. and *Erysipelothrix rhusiopathiae*.
Bacterial strains were isolated between 1999 and 2002 from cattle and pigs presenting diseases corresponding to target indications in Germany, France, The Netherlands and United Kingdom. From a sample of more than 350 isolates, 97.7% were found to be susceptible to cefquinome (resistance breakpoint of 4 µg/mL). These susceptible strains had MIC levels ranging from < 0.004 to 2 µg/mL.

Investigations which have been done between 2000 and 2004 on 304 *Mannheimia haemolytica* and *Pasteurella multocida* isolates have shown a susceptibility rate of 100 % with a MIC of ≤ 0.008 to 0.125 µg/ml (limiting concentration for susceptibility: 2 µg/ml).

Cefquinome as a fourth generation cephalosporin combines high cellular penetration and ß-lactamase stability. In contrast to cephalosporins of previous generations, cefquinome is not hydrolysed by chromosomally–encoded cephalosporinases of the Amp-C type or by plasmid mediated cephalosporinases of some enterobacterial species. However, some Extended Spectrum beta-lactamases (ESBL) can hydrolyse cefquinome and cephalosporins of other generations. The potential for resistance development against cefquinome is rather low. High-level resistance to cefquinome would require the coincidence of two genetic modifications, i.e. hyperproduction of specific ß-lactamases as well as decreased membrane permeability.

4.3 Pharmacokinetics

In cattle peak serum concentrations of about 2 µg/ml are reached within 1.5-2 hours after intramuscular or subcutaneous administration at the dose of 1 mg/kg. Cefquinome has a relatively short half-life (2.5 hours), is < 5 % protein bound and excreted unchanged in the urine. Cefquinome is not absorbed after oral administration.
In pigs or piglets, at 2 mg/kg dosage, maximum serum concentrations of around 5 µg/ml are measured within 15 to 60 minutes after intramuscular injection. The average half-life is about 9 hours.
Cefquinome binds poorly to plasma proteins and therefore penetrates into the cerebrospinal fluid (CSF) and the synovial fluid in pigs. The concentration profile is similar between the synovial fluid and the plasma. The concentrations reached in the CSF 12 hours after treatment are similar to those in plasma.

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: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25°C.
Protect from light.
Keep the bottle in the outer carton.

5.4 Nature and composition of immediate packaging

Cardboard box containing one 50 ml or 100ml colourless glass bottle, type II with a grey epichlorhydrine rubber stopper, fluoro polymer coated, type I closure and sealed with aluminum caps.

Cardboard box of one 50 ml glass bottle.
Cardboard box of one 100 ml glass bottle.

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.
{< >to be adjusted nationally}

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{DD month 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

[Not applicable for MRP/DCP/SRP and national procedures]

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{50 ml Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

COBACTAN 2.5% w/v suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

25 mg/mL Cefquinome (as cefquinome sulfate)

3. PACKAGE SIZE

50 ml

4. TARGET SPECIES

Cattle and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle (meat and offal)*:* 5 days
Cattle (milk)*:* 24 hours
Pig (meat and offal)*:* 3 days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Keep the bottle in the outer carton.

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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/0/00/000/000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{100 ml Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

COBACTAN 2.5% w/v suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

25 mg/mL Cefquinome (as cefquinome sulfate)

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Cattle and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle (meat and offal)*:* 5 days
Cattle (milk)*:* 24 hours
Pig (meat and offal)*:* 3 days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Keep the bottle in the outer carton.

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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/0/00/000/000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{50 ml Glass bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

COBACTAN 2.5% w/v suspension

2. STATEMENT OF ACTIVE SUBSTANCES

25 mg/ml Cefquinome (as cefquinome sulfate)

3. TARGET SPECIES

Cattle and pigs

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Cattle (meat and offal)*:* 5 days
Cattle (milk)*:* 24 hours
Pig (meat and offal)*:* 3 days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

Once opened use by:_____

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Keep the bottle in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{100 ml Glass bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

COBACTAN 2.5% w/v suspension

2. STATEMENT OF ACTIVE SUBSTANCES

25 mg/ml Cefquinome (as cefquinome sulfate)

3. TARGET SPECIES

Cattle and pigs

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Cattle (meat and offal)*:* 5 days
Cattle (milk)*:* 24 hours
Pig (meat and offal)*:* 3 days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

Once opened use by:_____

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Keep the bottle in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

COBACTAN 2.5% w/v suspension for injection for cattle and pigs

2. Composition

Each ml contains:

Active substance:
25 mg Cefquinome (as cefquinome sulfate)

Milky-white to slightly brownish suspension.

3. Target species

Cattle and pigs.

4. Indications for use

For the treatment of bacterial infections in cattle and pigs caused by the Gram-positive and Gram-negative microorganisms sensitive to cefquinome.

Cattle:
Respiratory disease caused by *Pasteurella multocida* and *Mannheimia haemolytica*
Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)
Acute *Escherichia coli* mastitis with signs of systemic involvement

Calves:
Escherichia coli septicaemia in calves

Pigs:
For the treatment of bacterial infections of the lungs and respiratory tract caused by *Pasteurella multocida, Haemophilus parasuis, Actinobacillus pleuropneumoniae, Streptococcus suis* and other cefquinome-sensitive organisms
Mastitis-Metritis-Agalactia syndrome (MMA) with involvement of *Escherichia coli, Staphylococcus* spp.*, Streptococcus* spp. and other cefquinome sensitive organisms

Piglets:
Reduction of mortality in cases of meningitis caused by *Streptococcus suis*.
For the treatment of:
Arthritis caused by *Streptococcus ssp., Escherichia coli* and other cefquinome-sensitive organisms.
Epidermitis (mild or moderate lesions) caused by *Staphylococcus hyicus.*

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, ß-lactam antibiotics or to any of the excipients.
Do not administer to animals less than 1.25 kg body weight.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

6. Special warnings

Special warnings:

Use of the veterinary medicinal product may constitute a risk to public health due to spread of antimicrobial resistance.
The veterinary medicinal product should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly to first line treatment. Official, national and regional antimicrobial policies should be taken into account when the product is used. Increased use, including use of the product deviating from the instructions given, may increase the prevalence of resistance. Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.

Special precautions for safe use in the target species:
The veterinary medicinal product is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
1. Do not handle this veterinary medicinal product if you know you are sensitized, or if you have been advised not to work with such preparation.
2. Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.
3. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.
4. Cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

Other precautions:
It is known that a cross sensitivity to cephalosporin exists for bacteria sensitive to the cephalosporin group.

Pregnancy and lactation:
There is no available information indicating reproductive toxicity in cattle or pigs. In reproduction toxicity studies in laboratory animals cefquinome did not reveal any effect on reproduction or teratogenic potential. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Due to undesirable pharmacodynamic interaction, do not apply cefquinome simultaneously with pharmaceuticals acting bacteriostatically.

Overdose:
Overdoses of 20 mg/kg/day in cattle and 10 mg/kg/day in pigs and piglets have been well tolerated.

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 and pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction, Injection site lesion[1]

[1] are repaired 15 days after the last administration

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: <{national system details}
{< >to be adjusted nationally}

8. Dosage for each species, routes and method of administration

Intramuscular use

Species	Indication	Dosage	Frequency
Cattle	Respiratory disease caused by *Pasteurella multocida* and *Mannheimia* haemolytica Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 3 or 5 consecutive days
	Acute *Escherichia coli* mastitis with signs of systemic involvement	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 2 consecutive days
Calves	*Escherichia coli* septicaemia	2 mg cefquinome/kg bw (4 ml/50 kg bw)	Once daily for 3 or 5 consecutive days
Pigs	Respiratory disease	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 3 consecutive days.
	MMA	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 2 consecutive days.
Piglets	Meningitis Arthritis Epidermitis	2 mg Cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 5 consecutive days

Studies have indicated the advisability of giving second and subsequent injections at a different injection site. The preferred injection site is in muscular tissue in the mid neck.
Shake the vial well before using.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
The veterinary medicinal product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry sterile needle and syringe. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes, for example when treating piglets. The cap may be safely punctured up to 25 times. The 50ml vial should be used for treating small piglets. When treating groups of animals, use a draw-off needle.

10. Withdrawal periods

Cattle (meat and offal): 5 days
Cattle (milk): 24 hours
Pig (meat and offal): 3 days

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Protect from light.
Keep the bottle in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle 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.
{< >to be adjusted nationally}

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.
{< >to be adjusted nationally}

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Cardboard box of one 50 ml glass bottle.
Cardboard box of one 100 ml glass bottle.

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 manufacturer responsible for batch release>

Manufacturer responsible for batch release:
Intervet International GmbH
Feldstrasse 1a
85716 Unterschleissheim
Germany

Intervet Productions S.r.l.
Via Nettunense km 20,300
04011 Aprilia
Italy

<Local representatives <and contact details to report suspected adverse reactions>:>
{< >to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
{< >to be adjusted nationally}