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

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Name	Countries
Clavaseptin 750 mg palatable tablets for dogs	Bulgaria, Cyprus, Greece, Czech Republic, Hungary, Ireland, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, UK
Clavaseptin P 750 mg tablets for dogs	France, Luxembourg
Clavaseptin 750 mg, tablets for dogs	Austria, Belgium, Estonia, Germany, Italy, Netherlands, Portugal, Spain
Clavaseptin 600mg/150mg tablets for dogs	Denmark, Finland, Sweden

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:
Amoxicillin.....600 mg
(Corresponding to amoxicillin trihydrate)……688.69 mg
Clavulanic acid..... 150 mg
(Corresponding to potassium clavulanate)……. 178,69 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal produc**t
Brown iron oxide E172	1,43 mg
Crospovidone	
Povidone K25	
Silicon dioxide	
Microcrystalline cellulose	
Pig liver flavour	
Dried yeast	
Magnesium stearate	
Hypromellose	

Oblong, off -white to brownish speckled, scored tablets of about 24 mm. Tablet can be divided into four equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of infections caused by bacteria susceptible to amoxicillin in combination with clavulanic acid (including beta-lactamase producing strains), in particular:

- Skin infections (including deep and superficial pyodermas, wounds, abscesses) caused by *Staphylococcus* spp, *Streptococcus* spp and *Pasteurella* spp.
- Respiratory tract infections (sinusitis, rhino-tracheitis, bronchopneumonia) caused by *Staphylococcus* spp and *E. coli*.
- Infections of the oral cavity (mucous membranes) caused by *Streptococcus* spp, and *Pasteurella* spp.
- Urinary tract infections (nephritis, cystitis) caused by *E. coli*, *Klebsiella* spp and *Proteus mirabilis.*
- Digestive tract infections, especially gastroenteritis caused by *E. coli.*

3.3 Contraindications

Do not use in cases of hypersensitivity to penicillins or other substances of the β-lactam group or to any of the excipients.
Do not administer to gerbils, guinea pigs, hamsters, rabbits and chinchillas or other small herbivores.
Do not use in animals with serious dysfunction of the kidneys accompanied by anuria or oliguria.
Do not administer to horses and ruminating animals.

3.4 Special warnings

Cross-resistance has been shown between amoxicillin/clavulanic acid and β-lactam antibiotics. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to βlactam antibiotics because its effectiveness may be reduced.
Methicillin resistant *S. aureus* (MRSA) and methicillin resistant *S. pseudintermedius* (MRSP) have been isolated in cats and dogs with proportion of resistance that varies across EU countries.
Do not use in cases of known resistance to the combination of amoxicillin and clavulanic acid.
Do not use in cases of suspected or confirmed MRSA/MRSP infections, as isolates should be considered resistant to all β-lactam including amoxicillin/clavulanic acid combination.
High resistances (up to 100%) have been reported in *E. coli* isolates from skin and soft tissue infections in dogs.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In animals with impaired liver and kidney function, the use of the veterinary medicinal product should be subject to a benefit/risk evaluation by the veterinary surgeon and the posology evaluated carefully.

Use of the veterinary medicinal 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 local/regional level.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

Aminopenicillins in combination with beta-lactamase inhibitors are in AMEG category „C". 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.
Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.
The potential for allergic cross-reactivity with other penicillins should be considered.

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

Penicillins and cephalosporins may cause hypersensitivity (allergy) 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.

Do not handle this veterinary medicinal product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning.
Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
Wash hands after handling the tablets.

Accidental ingestion of the veterinary medicinal product by a child may be harmful. To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the carton.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[1], Diarrhoea.[1] Hypersensitivity reaction (Allergic skin reactions[2]), anaphylaxis[2]

[1)] Treatment may be discontinued depending on the severity of the undesirable effects and a benefit/risk evaluation by the veterinary surgeon
[2)] In these cases, administration should be discontinued and a symptomatic treatment given

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:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Laboratory studies in rats have not produced any evidence of teratogenic, foetotoxic or maternotoxic 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

The bactericidal activity of amoxicillin may be reduced by the simultaneous use of bacteriostatic substances such as macrolides, tetracyclines, sulfonamides and chloramphenicol.
Penicillins may increase the effect of aminoglycosides.

3.9 Administration routes and dosage

Oral use.

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

The recommended dose of the veterinary medicinal product is 10 mg amoxicillin / 2.5 mg clavulanic acid per kg body weight twice a day, i.e. 1 tablet per 60 kg body weight every 12 h, for 5 to 7 days, according to the following table:

Bodyweight (kg)	Number of tablets twice daily
[20.1 - 30]	½
[30.1 - 45]	¾
[45.1 - 60]	1
[60.1 - 75]	1 ¼
[75.1 - 90]	1 ½

In severe cases, the dose can be doubled at the discretion of the responsible veterinarian.

Duration of the treatment:
For all indications, a treatment of 5 to 7 days is sufficient in the majority of cases.
For chronic or recurrent cases, it may be necessary to continue treatment for 2 to 4 weeks.

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

At three times the recommended dose for a period of 28 days, diarrhoea was observed in dogs. In the event of an overdose symptomatic treatment is advised.

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

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01CR02

4.2 Pharmacodynamics

Amoxicillin is an aminobenzylpenicillin from the β-lactam penicillin family which prevents the bacterial cell wall formation by interfering with the final step of peptidoglycan synthesis.

Clavulanic acid is an irreversible inhibitor of intracellular and extracellular β-lactamases which protects amoxicillin from inactivation by many β-lactamases.

Amoxicillin/clavulanate has a wide range of activity which includes β-lactamase producing strains of both Gram-positive and Gram-negative aerobes, facultative anaerobes and obligate anaerobes. The antimicrobial spectrum relevant for dog's indications is summarized in the table below.

Summary of susceptibility for dog target bacteria:

Target bacteria in each indication	n	Range of MIC (µg/mL)	MIC50 (µg/mL)	MIC90 (µg/mL)	Clinical breakpoints (I/R)
Skin and soft tissues					
Staphylococcus spp	431*	0.03-32	0.12	1	0.25/1
S. aureus	38*	0.12-16	0.5	2	0.25/1
S. intermedius group	343*	0.03-8	0.12	0.5	0.25/1
Coagulase-negative *Staphylococcus* spp	49*	0.03-32	0.12	2	0.25/1
Streptococcus spp	142*	0.015-0.06	≤0.015	≤0.015	-
Streptococcus canis	127*	0.015-0.06	≤0.015	≤0.015	-
Streptococcus dysgalactiae	12*	0.015	≤0.015	≤0.015	-
Pasteurella spp	22*	0.03-0.25	0.12	0.25	-
Respiratory					
Staphylococcus spp	112*	0.06-8	0.12	0.5	-
S. intermedius group	90*	0.06-8	0.12	0.25	-
S. aureus	22*	0.12-8	0.25	1	-
Dental					
Streptococcus spp	16**	0.008 - 1	0.014	0.4	-
Pasteurella spp	68**	0.03 - 64	0.124	0.4	-
Urinary					
Escherichia coli	236*	1-32	4	16	8/-
Klebsiella spp	33*	0.5-32	2	32	8/-
Proteus spp	66*	0.5-16	1	8	8/-
Digestive					
Escherichia coli	- *	1-32	4	8	-

Breakpoints are from CLSI VET01-S7.
* MIC values determined from bacteria collected in Europe in 2021-2022 (ComPath-IV survey). Susceptibility of digestive isolates is assumed similar to that of the same bacteria in other types of infection.
** MIC values determined from bacteria collected from dog dental infections in Europe in 2002.
- Missing information.

The two main mechanisms of resistance to amoxicillin/clavulanic acid are inactivation by β-lactamases that are not inhibited by clavulanic acid, and alteration of penicillin binding proteins, which lead to co-resistance to other β-lactam antibiotics. Impermeability of bacteria or efflux pump mechanisms may also contribute to bacterial resistance, including co- and cross-resistance. Susceptibility and resistance patterns can vary with geographical area and bacterial strain, and may change over time.
Pseudomonas spp are naturally resistant to the amoxicillin – clavulanic acid combination. Methicillin resistant *S. aureus* (MRSA) and methicillin resistant *S. pseudintermedius* (MRSP) isolates have been identified in cats and dogs and should be considered resistant to all β-lactam including amoxicillin/clavulanic acid combination.
High resistances (up to 100%) have been reported in *E. coli* isolates from skin and soft tissue infections in dogs.

4.3 Pharmacokinetics

After oral administration at the recommended dose in dogs, the absorption of amoxicillin and clavulanic acid is fast. The maximum plasma concentration of amoxicillin of 8.5 µg/ml is reached in 1.4 hours and the maximum plasma concentration of clavulanic acid of 0.9 µg/ml is reached in 0.9 hours. Half-life is 1 hour in dogs for both substances.

Elimination is also fast. 12 % of the amoxicillin and 17 % of clavulanic acid is excreted in the urine. The remainder is excreted as inactive metabolites.
After repeated oral administration of the recommended dose, there is no accumulation of amoxicillin or clavulanic acid and the steady state is reached rapidly after first administration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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: 48 hours.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Return any part of the tablet to the opened blister-pack and use within 48 h.

5.4 Nature and composition of immediate packaging

Aluminium/aluminium (oPA/Alu/PE) blister pack with 10 tablets/blister
Cardboard box: Pack sizes of 10, 100, 250, and 600 tablets.
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

[To be completed nationally]

7. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: [To be completed nationally]

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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Name	Countries
Clavaseptin 750 mg palatable tablets for dogs	Bulgaria, Cyprus, Greece, Czechia, Hungary, Ireland, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, UK
Clavaseptin P 750 mg tablets for dogs	France, Luxembourg
Clavaseptin 750 mg, tablets for dogs	Austria, Belgium, Estonia, Germany, Italy, Netherlands, Portugal, Spain
Clavaseptin 600mg/150mg tablets for dogs	Denmark, Finland, Sweden

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Amoxicillin.....600 mg
(Corresponding to amoxicillin trihydrate)……..688.69 mg
Clavulanic acid..... 150 mg
(Corresponding to potassium clavulanate)…….. 178,69 mg

3. PACKAGE SIZE

10, 100, 250, 600 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Not applicable.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Shelf life after first opening the immediate packaging: 48 hours.
Return any divided tablet to the opened blister-pack and use within 48 hours.

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

[To be completed nationally]

14. MARKETING AUTHORISATION NUMBERS

[To be completed nationally]

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavaseptin 750 mg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Amoxicillin 600 mg
Clavulanic acid 150 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Name	Countries
Clavaseptin 750 mg palatable tablets for dogs	Bulgaria, Cyprus, Greece, Czechia, Hungary, Ireland, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, UK
Clavaseptin P 750 mg tablets for dogs	France, Luxembourg
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Clavaseptin 600mg/150mg tablets for dogs	Denmark, Finland, Sweden

2. Composition

Each tablet contains:

Active substances:
Amoxicillin.....600 mg
(Corresponding to amoxicillin trihydrate)……688.69 mg
Clavulanic acid.....150 mg
(Corresponding to potassium clavulanate)……..... 178,69 mg

Excipients:
Iron oxide, brown (E172)……1,43 mg

Oblong, off -white to brownish speckled, scored tablets of about 24 mm. Tablet can be divided into four equal parts.

3. Target species


Dogs.

4. Indications for use

Treatment of infections caused by bacteria susceptible to amoxicillin in combination with clavulanic acid (including beta-lactamase producing strains), in particular:

- Skin infections (including deep and superficial pyodermas, wounds, abscesses) caused by *Staphylococcus* spp, *Streptococcus* spp and *Pasteurella* spp.
- Respiratory tract infections (sinusitis, rhino-tracheitis, bronchopneumonia) caused by *Staphylococcus* spp, and *E. coli.*
- Infections of the oral cavity (mucous membranes) caused by *Streptococcus* spp, and *Pasteurella* spp.
- Urinary tract infections (nephritis, cystitis) caused by, *E. coli*, *Klebsiella* spp and *Proteus mirabilis.*
- Digestive tract infections, especially gastroenteritis caused by *E. coli.*

5. Contraindications

Do not use in cases of hypersensitivity to penicillins or other substances of the β-lactam group or to any of the excipients.
Do not administer to gerbils, guinea pigs, hamsters, rabbits and chinchillas or other small herbivores.
Do not use in animals with serious dysfunction of the kidneys accompanied by anuria or oliguria.
Do not administer to horses and ruminating animals.

6. Special warnings

Special warnings:

Cross-resistance has been shown between amoxicillin/clavulanic acid and β-lactam antibiotics. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to β-lactam antibiotics because its effectiveness may be reduced.
Methicillin resistant *S. aureus* (MRSA) and methicillin resistant *S. pseudintermedius* (MRSP) have been isolated in cats and dogs with proportion of resistance that varies across EU countries.
Do not use in cases of known resistance to the combination of amoxicillin and clavulanic acid.
Do not use in cases of suspected or confirmed MRSA/MRSP infections, as isolates should be considered resistant to all β-lactam including amoxicillin/clavulanic acid combination.
High resistances (up to 100%) have been reported in *E. coli* isolates from skin and soft tissue infections in dogs.

Special precautions for safe use in the target species:

In animals with impaired liver and kidney function, the use of the veterinary medicinal product should be subject to a benefit/risk evaluation by the veterinary surgeon and the posology evaluated carefully.

Use of the veterinary medicinal 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 local/regional level.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

Aminopenicillins in combination with beta-lactamase inhibitors are in AMEG category „C". 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.
Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.
The potential for allergic cross-reactivity with other penicillins should be considered.

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

Penicillins and cephalosporins may cause hypersensitivity (allergy) 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.
Do not handle this veterinary medicinal product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning.
Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

Wash hands after handling the tablets.

Accidental ingestion of the veterinary medicinal product by a child may be harmful. To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the carton.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Laboratory studies in rats have not produced any evidence of harmful effects to the foetus or the mother.
Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

The bactericidal activity of amoxicillin may be reduced by the simultaneous use of bacteriostatic substances such as macrolides, tetracyclines, sulfonamides and chloramphenicol.
Penicillins may increase the effect of aminoglycosides.

Overdose:
At three times the recommended dose for a period of 28 days, diarrhoea was observed in dogs. In the event of an overdose symptomatic treatment is advised.

Major incompatibilities:
None known.

7. Adverse events

Dogs.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[1], Diarrhoea.[1] Hypersensitivity reaction (Allergic skin reactions[2]), anaphylaxis[2]

[1)] Treatment may be discontinued depending on the severity of the undesirable effects and a benefit/risk evaluation by the veterinary surgeon
[2)] In these cases, administration should be discontinued and a symptomatic treatment given

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 its 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

Oral use.

The recommended dose of the veterinary medicinal product is 10 mg amoxicillin / 2.5 mg clavulanic acid per kg body weight twice a day, i.e. 1 tablet per 60 kg body weight every 12 h, for 5 to 7 days, according to the following table:

Bodyweight (kg)	Number of tablets twice daily
[20.1 - 30]	½
[30.1 - 45]	¾
[45.1 - 60]	1
[60.1 - 75]	1 ¼
[75.1 - 90]	1 ½

In severe cases, the dose can be doubled at the discretion of the responsible veterinarian.

Duration of the treatment:
For all indications, a treatment of 5 to 7 days is sufficient in the majority of cases.
For chronic or recurrent cases, it may be necessary to continue treatment for 2 to 4 weeks.

9. Advice on correct administration

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

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf life after first opening the immediate packaging: 48 hours.
Return any part of tablet to the opened blister -pack and use within 48 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the 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 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

Pack-sizes of 10, 100, 250, 600 tablets. Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY [To be completed nationally]

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 and contact details to report suspected adverse reactions:

[To be completed nationally]

Manufacturer responsible for batch release: Vetoquinol S.A Magny-Vernois 70200 Lure, France.

<Local representatives <and contact details to report suspected adverse reactions>:>*[To be completed nationally]*