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

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindabactin 220 mg chewable tablets for dogs (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FR, FI, HR, HU, IE, IS, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE SI, SK, UK(NI))

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Clindamycin (as clindamycin hydrochloride) 220 mg

Excipients:

Qualitative composition of excipients and other constituents
Croscarmellose sodium
Starch, pregelatinized (maize)
Cellulose, microcrystalline
Silica, colloidal hydrated
Yeast (dried)
Chicken Flavour
Magnesium stearate

Light brown with brown spots, round and convex chewable flavoured 13 mm tablet with a cross-shaped break line on one side.

Tablets can be divided into 2 or 4 equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the treatment of infected wounds and abscesses, and oral cavity infections including periodontal disease, caused by or associated with *Staphylococcus* spp., *Streptococcus* spp. (except *Streptococcus faecalis*), *Bacteroides* spp., *Fusobacterium necrophorum*, and *Clostridium perfringens* susceptible to clindamycin.
For the treatment of superficial pyoderma associated with *Staphylococcus pseudintermedius* susceptible to clindamycin.
For the treatment of osteomyelitis, caused by *Staphylococcus aureus* susceptible to clindamycin.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients or to lincomycin. Do not administer to rabbits, hamsters, guinea pigs, chinchillas, horses and ruminants, because ingestion of clindamycin by these species can cause severe gastro-intestinal disturbance which may result in death.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Use of the veterinary medicinal product should be based on susceptibility testing of the target bacteria isolated from the animal. If this is not possible, therapy should be based on local 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.

Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to clindamycin and may decrease the effectiveness of treatment with lincomycin or macrolide antibacterials due to the potential for cross-resistance.

Cross-resistance has been demonstrated among lincosamides (including clindamycin), erythromycin and other macrolides.

In some cases (localised or mild lesions; to prevent recurrence), superficial pyoderma can be treated topically. The need for and duration of systemic antimicrobial treatment should be based on careful consideration of the individual case.

During prolonged therapy of one month or greater, periodic liver and kidney function tests and blood counts should be performed.

Animals with severe renal and/or very severe hepatic disturbances accompanied by severe metabolic aberrations should be dosed with caution and should be monitored by serum examination during high-dose clindamycin therapy.

The use of the veterinary medicinal product is not recommended in neonates.

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

Lincosamides (lincomycin, clindamycin, pirlimycin) may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to lincosamides should avoid contact with the veterinary medicinal product.
Wash hands after handling tablets.
Accidental ingestion may result in gastro-intestinal effects such as abdominal pain and diarrhoea. Care should be taken to avoid accidental ingestion.
In order to reduce the risk of accidental ingestion by children, do not take the tablets out of the blister until ready to administer to the animal. Return part-used tablets into the blister and carton and use at the subsequent administration.
In case of accidental ingestion, particularly by children, 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:

Uncommon (1 to 10 animals / 1,000 animals treated):	Vomiting, diarrhoea, disorder of gastrointestinal flora[a]

[a] Clindamycin causes overgrowth of non-sensitive organisms such as resistant clostridia and yeasts. In cases of superinfection, appropriate measures must be taken according to the clinical situation.

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:

While high dose studies in rats suggest that clindamycin is not a teratogen and does not significantly affect the breeding performance of males and females, safety in gestating bitches or breeding male dogs has not been established.
Clindamycin crosses the placental and the blood-milk barrier.
Treatment of lactating females can cause diarrhea in puppies.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Clindamycin hydrochloride has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. The veterinary medicinal product should be used with caution in animals receiving such agents.
Aluminium salts and hydroxides, kaolin and aluminium-magnesium-silicat complex may reduce the absorption of lincosamides. These digestive substances should be administered at least 2 hours before clindamycin.
Clindamycin should not be used concomitantly with or immediately after erythromycin or other macrolides to prevent macrolide-induced resistance to clindamycin.
Clindamycin may reduce plasma levels of cyclosporine with a risk of lack of activity.
During the simultaneous use of clindamycin and aminoglycosides (e.g.gentamicin), the risk of adverse interactions (acute renal failure) cannot be excluded.
Clindamycin should not be used concomitantly with chloramphenicol or macrolides as they antagonise each other at their site of action at the 50S ribosomal sub-unit.

3.9 Administration routes and dosage

Oral use.

1. For the treatment of infected wounds and abscesses, and oral cavity infections including periodontal disease, administer either:

- 5.5 mg clindamycin/kg bodyweight every 12 hours for 7-10 days, or
- 11 mg clindamycin/kg bodyweight every 24 hours for 7-10 days

If no clinical response is seen within 4 days, redetermine the diagnosis.

2. For the treatment of superficial pyoderma, administer either:

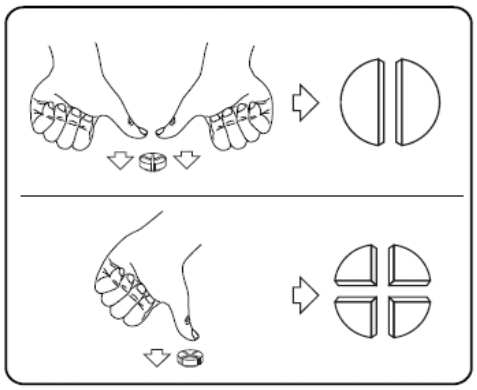
- 5.5 mg clindamycin/kg bodyweight every 12 hours, or
- 11 mg clindamycin/kg bodyweight every 24 hours

Therapy of canine superficial pyoderma is usually recommended for 21 days, with shortening or extension of therapy based on clinical judgement.

3. For the treatment of osteomyelitis, administer:
- 11 mg clindamycin/kg bodyweight every 12 hours for a minimum of 28 days

If no clinical response is seen within 14 days, the treatment should be stopped and the diagnosis redetermined.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid under-dosing.
Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



2 equal parts: press down with your thumbs on both sides of the tablet.
4 equal parts: press down with your thumb in the middle of the tablet.

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

Oral doses of clindamycin up to 300 mg/kg/day did not result in toxicity. Dogs receiving 600 mg/kg/day of clindamycin developed anorexia, vomiting and weight loss. In cases of overdose, discontinue treatment immediately and establish symptomatic treatment.

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

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QJ01FF01

4.2 Pharmacodynamics

Mode of action
Clindamycin is a semi-synthetic antibiotic produced by 7(S)-chloro substitution of the 7(R)-hydroxy group of the natural antibiotic produced by *Streptomyces lincolnensis var. lincolnensis*.
Clindamycin, a mainly time-dependent acting antibiotic, acts by a bacteriostatic mechanism where the drug interferes with protein synthesis within the bacterial cell, thus inhibiting the growth and multiplication of the bacteria.

Clindamycin binds to the 23S ribosomal RNA component of the 50S subunit. This prevents amino acids binding on these ribosomes, and therefore inhibits peptide bond formation. The ribosomal sites are close to those bound by macrolides, streptogramins or chloramphenicol.

Antibacterial spectrum
Clindamycin is a moderate spectrum antimicrobial drug.
Clindamycin has in vitro activity against the following micro-organisms:

- Aerobic Gram-positive cocci, including: *Staphylococcus pseudintermedius* and *Staphylococcus aureus* (penicillinase and non-penicillinase producing strains), *Streptococcus* spp. (except *Streptococcus faecalis*).
- Anaerobic Gram-negative bacilli, including: *Bacteroides* spp*., Fusobacterium necrophorum*.
- Clostridia: Most *C. perfringens* are susceptible.

MIC data
CLSI clindamycin veterinary breakpoints are available for *Staphylococcus* spp. and *Streptococci*-β-haemolytic group in skin and soft tissue infections: S ≤0.5µg/ml; I=1-2µg/ml; R≥4µg/ml (CLSI February 2018).

Type and mechanism of resistance
Clindamycin belongs to the lincosamide group of antibiotics. Resistance can develop to the lincosamides alone, but more commonly cross-resistance occurs among macrolides, lincosamides and streptogramin B antibiotics (MLSB group). Resistance is the result of methylation of adenine residues in the 23S RNA of the 50S ribosomal subunit, which prevents drug binding to the target site. Different bacterial species are able to synthesize an enzyme, encoded by a series of structurally related erythromycin ribosomal methylase (*erm*) genes. In pathogenic bacteria, these determinants are mostly borne by plasmids and transposons that are self-transferable. The erm genes occur predominantly as variants erm(A) and erm(C) in *Staphylococcus aureus* and as variant erm(B) in *Staphylococcus pseudintermedius*, streptococci and enterococci. Bacteria resistant to macrolides but initially susceptible to clindamycin, rapidly develop resistance to clindamycin when exposed to macrolides. These bacteria present a risk of *in vivo* selection of constitutive mutants.
MLSB inducible resistance is not detected by standard in vitro susceptibility testing methods. The CLSI recommends the D-zone test to be routinely performed in veterinary diagnostic laboratories in order to detect clinical isolates with inducible resistance phenotype. Clindamycin use should be discouraged in these patients.
The incidence of resistance to lincosamides in *Staphylococcus* spp. appears to be wide-ranging in Europe. Studies (2010) report an incidence between 25 to 40%.

4.3 Pharmacokinetics

Absorption:
Clindamycin hydrochloride is rapidly absorbed from the canine gastrointestinal tract following oral administration. After oral administration of the veterinary medicinal product to dogs (10.8 mg/kg), bioavailability was 63%.

Serum values:
After oral administration of 10.8 mg/kg bodyweight to dogs, the maximal concentration of 6.1 µg/ml (mean C_{max}) is reached within 1 hour (median T_{max}). The plasma elimination half-life of clindamycin in the dog is approximately 3.5 hours. No accumulation of bioactivity has been observed in dogs after several oral administrations.

Metabolism and Excretion:
Extensive research of the metabolism and excretion pattern of clindamycin shows that the parent molecule as well as bioactive and bio-inactive metabolites are excreted via the urine and faeces. Nearly all bioactivity in the serum following oral administration is due to the parent molecule (clindamycin).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

Aluminium - Polyamide/Aluminium/PVC blister
Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or 25 blisters of 10 tablets.
Cardboard box containing 10 separate cardboard boxes, each containing 1 blister of 10 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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

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

Cardboard box
Multipack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindabactin 220 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains: 220 mg clindamycin (as clindamycin hydrochloride)

3. PACKAGE SIZE

10 tablets
20 tablets
30 tablets
40 tablets
50 tablets
60 tablets
70 tablets
80 tablets
90 tablets
100 tablets
250 tablets

10 × 10 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life of divided tablets: 3 days.

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Aluminium-Polyamide/Aluminium/PVC blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindabactin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Clindamycin (as clindamycin hydrochloride) 220mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life of divided tablets: 3 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Clindabactin 220 mg chewable tablets for dogs

2. Composition

Each tablet contains:

Active substance:
Clindamycin (as clindamycin hydrochloride) 220 mg

Light brown with brown spots, round and convex chewable flavoured 13 mm tablet with a cross-shaped break line on one side.

Tablets can be divided into 2 or 4 equal parts.

3. Target species

Dogs.

4. Indications for use

For the treatment of infected wounds and abscesses, and oral cavity infections including periodontal disease, caused by or associated with *Staphylococcus* spp., *Streptococcus* spp. (except *Streptococcus faecalis*), *Bacteroides* spp., *Fusobacterium necrophorum*, and *Clostridium perfringens* susceptible to clindamycin.
For the treatment of superficial pyoderma associated with *Staphylococcus pseudintermedius* susceptible to clindamycin.
For the treatment of osteomyelitis, caused by *Staphylococcus aureus* susceptible to clindamycin.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients or to lincomycin. Do not administer to rabbits, hamsters, guinea pigs, chinchillas, horses and ruminants, because ingestion of clindamycin by these species can cause severe gastro-intestinal disturbance which may result in death.

6. Special warnings

Special precautions for safe use in the target species:
The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Use of the veterinary medicinal product should be based on susceptibility testing of the target bacteria isolated from the animal. If this is not possible, therapy should be based on local 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.

Use of the veterinary medicinal product deviating from the instructions given in the package leaflet may increase the prevalence of bacteria resistant to clindamycin and may decrease the effectiveness of treatment with lincomycin or macrolide antibacterials due to the potential for cross-resistance.

Cross-resistance has been demonstrated among lincosamides (including clindamycin), erythromycin and other macrolides.

In some cases (localised or mild lesions; to prevent recurrence), superficial pyoderma can be treated topically. The need for and duration of systemic antimicrobial treatment should be based on careful consideration of the individual case.

During prolonged therapy of one month or greater, periodic liver and kidney function tests and blood counts should be performed.

Animals with severe renal and/or very severe hepatic disturbances accompanied by severe metabolic aberrations should be dosed with caution and should be monitored by serum examination during high-dose clindamycin therapy.

The use of the veterinary medicinal product is not recommended in neonates.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Lincosamides (lincomycin, clindamycin, pirlimycin) may cause hypersensitivity (allergy) reactions.
People with known hypersensitivity to lincosamides should avoid contact with the veterinary medicinal product.
Wash hands after handling tablets.
Accidental ingestion may result in gastro-intestinal effects such as abdominal pain and diarrhoea. Care should be taken to avoid accidental ingestion.
In order to reduce the risk of accidental ingestion by children, do not take the tablets out of the blister until ready to administer to the animal. Return part-used tablets into the blister and carton and use at the subsequent administration.
In case of accidental ingestion, particularly by children, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
While high dose studies in rats suggest that clindamycin is not a teratogen and does not significantly affect the breeding performance of males and females, safety in gestating bitches or breeding male dogs has not been established.
Clindamycin crosses the placental and the blood-milk barrier.
Treatment of lactating females can cause diarrhea in puppies.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Clindamycin hydrochloride has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. The veterinary medicinal product should be used with caution in animals receiving such agents.
Aluminium salts and hydroxides, kaolin and aluminium-magnesium-silicat complex may reduce the absorption of lincosamides. These digestive substances should be administered at least 2 hours before clindamycin.
Clindamycin should not be used concomitantly with or immediately after erythromycin or other macrolides to prevent macrolide-induced resistance to clindamycin.
Clindamycin may reduce plasma levels of cyclosporine with a risk of lack of activity.
During the simultaneous use of clindamycin and aminoglycosides (e.g. gentamicin), the risk of adverse interactions (acute renal failure) cannot be excluded.
Clindamycin should not be used concomitantly with chloramphenicol or macrolides as they antagonise each other at their site of action at the 50S ribosomal sub-unit.

Overdose:
Oral doses of clindamycin up to 300 mg/kg/day did not result in toxicity. Dogs receiving 600 mg/kg/day of clindamycin developed anorexia, vomiting and weight loss. In cases of overdose, discontinue treatment immediately and establish symptomatic treatment.

7. Adverse events

Dogs:

Uncommon (1 to 10 animals / 1,000 animals treated):	Vomiting, diarrhoea, disorder of gastrointestinal flora[a]

[a] Clindamycin causes overgrowth of non-sensitive organisms such as resistant clostridia and yeasts. In cases of superinfection, appropriate measures must be taken according to the clinical situation.

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

Oral use.
1. For the treatment of infected wounds and abscesses, and oral cavity infections including periodontal disease, administer either:
- 5.5 mg clindamycin/kg bodyweight every 12 hours for 7-10 days, or
- 11 mg clindamycin/kg bodyweight every 24 hours for 7-10 days

If no clinical response is seen within 4 days, redetermine the diagnosis.

2. For the treatment of superficial pyoderma, administer either:
- 5.5 mg clindamycin/kg bodyweight every 12 hours, or
- 11 mg clindamycin/kg bodyweight every 24 hours

Therapy of canine superficial pyoderma is usually recommended for 21 days, with shortening or extension of therapy based on clinical judgement.

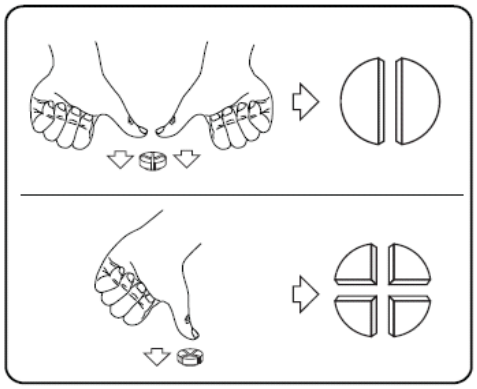
3. For the treatment of osteomyelitis, administer:
- 11 mg clindamycin/kg bodyweight every 12 hours for a minimum of 28 days

If no clinical response is seen within 14 days, the treatment should be stopped and the diagnosis redetermined.

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid under-dosing.

9. Advice on correct administration

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



2 equal parts: press down with your thumbs on both sides of the tablet.
4 equal parts: press down with your thumb in the middle of the tablet.

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.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.
The expiry date refers to the last day of that month.

Shelf life of divided tablets after first opening the immediate packaging: 3 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

Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or 25 blisters of 10 tablets.
Cardboard box containing 10 separate cardboard boxes, each containing 1 blister of 10 tablets.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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:

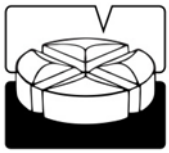
Manufacturer responsible for batch release:
Lelypharma B.V.
Zuiveringweg 42
8243 PZ Lelystad
The Netherlands

Genera d.d.
Svetonedeljska cesta 2, Kalinovica
10436 Rakov Potok
Croatia

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information



Divisible tablet