ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zodon 25 mg/ml oral solution for cats and dogs
Zodon vet 25 mg/ml oral solution for cats and dogs (BE, LU, NL)
Givix vet 25 mg/ml oral solution for cats and dogs (DK, FI, NO, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Clindamycin .....25 mg
(equivalent to 27,15 mg clindamycin hydrochloride)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ethanol 96% (E1510)	72 mg
Glycerol	
Sorbitol liquid (non crystallising)	
Sucrose	
Propylene glycol	
"Grilled" flavour	
Citric acid monohydrate	
Purified water	

Clear, amber solution

3. CLINICAL INFORMATION

3.1 Target species

Cats and dogs.

3.2 Indications for use for each target species

Cats:
For the treatment of infected wounds and abscesses caused by clindamycin-susceptible species of *Staphylococcus spp* and *Streptococcus spp*.

Dogs:
- For the treatment of infected wounds, abscesses and oral cavity/dental infections caused by or associated with clindamycin-sensitive species of *Staphylococcus spp*, *Streptococcus spp*, *Bacteroides spp*, *Fusobacterium necrophorum*, *Clostridium perfringens*
- Adjunctive treatment of mechanical or surgical periodontal therapy in the treatment of infections of the gingival and periodontal tissues
- For the treatment of osteomyelitis caused by *Staphylococcus aureus*

3.3 Contraindications

Do not use in hamsters, guinea pigs, rabbits, chinchillas, horses or ruminants because clindamycin ingestion by these species may cause severe gastrointestinal disorders.
Do not use in cases of hypersensitivity to the active substances, to lincomycin or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species
Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to clindamycin. Whenever possible, clindamycin should only be used based on susceptibility testing including the D-zone test.
Official national and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.
Clindamycin is likely to favour the proliferation of non-susceptible organisms such as resistant *Clostridia spp* and yeasts. In case of secondary infection, appropriate corrective measures should be taken based on clinical observations.
Clindamycin shows parallel-resistance with lincomycin and co-resistance with erythromycin. There is a partial cross-resistance to erythromycin and other macrolides.
In case of administration of high doses of clindamycin or during prolonged therapy of one month or greater, tests for liver and renal functions and blood counts should be performed periodically.
In dogs and cats with kidney problems and/or liver problems, accompanied by severe metabolic aberrations, the dose to be administered should be carefully determined and their condition should be monitored by performing appropriate blood tests during treatment.
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
Wash hands carefully after use.

People with known hypersensitivity to lincosamides (clindamycin and lincomycin) should avoid contact with the veterinary medicinal product.
Care should be taken to avoid accidental ingestion as this may result in gastro-intestinal effects such as abdominal pain and diarrhoea.
In case of accidental ingestion, particularly by a child, or allergic reaction 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

Cats, dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting, Diarrhoea

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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
While high dose studies in rats suggests that clindamycin is not a teratogen and does not significantly affect the breeding performance of males and females, the safety of the veterinary medicinal product in pregnant bitches/queens or breeding male dogs/cats has not been established.
Use only according to the benefit/risk assessment by the responsible veterinarian.
Clindamycin can pass the placenta and blood-milk barrier. As a consequence, treatment of lactating females can cause diarrhoea in puppies and kittens.

3.8 Interaction with other medicinal products and other forms of interaction

Aluminium salts and hydroxides, kaolin and Aluminium-Magnesium-Silicate complex may reduce the gastrointestinal absorption of lincosamides. Products containing these substances should be administered at least 2 hours before clindamycin.
Cyclosporin: clindamycin may reduce levels of this immunosuppressive drug with a risk of lack of activity.
Neuro-muscular blocking agents: Clindamycin possesses intrinsic neuromuscular blocking activity and should be used cautiously with other neuromuscular blocking agents (curares). Clindamycin may increase neuromuscular blockade.
Do not use clindamycin simultaneously with chloramphenicol or macrolides as they both target the ribosome 50S subunit and antagonist effects may develop.
When using clindamycin and aminoglycosides (e.g. gentamicin) simultaneously, the risk of adverse interactions (acute renal failure) cannot be excluded.

3.9 Administration routes and dosage

Oral use.

Recommended dose:
Cats:

- Infected wounds, abscesses: 11mg of clindamycin per kg of body weight per 24h or 5.5 mg /kg per 12h for 7 to 10 days.

The treatment should be stopped if no therapeutic effect is observed after 4 days.

Dogs:

- Infected wounds, abscesses and oral cavity/dental infections: 11 mg clindamycin per kg of body weight per 24h or 5.5 mg /kg per 12h for 7 to 10 days.

The treatment should be stopped if no therapeutic effect is observed after 4 days.

- Treatment of bone infections (osteomyelitis): 11 mg clindamycin per kg of body weight every 12 hours for a period of 28 days minimum. The treatment should be discontinued if no therapeutic effect is observed in the first 14 days.

- Dosage	- Volume to be administered per kg bodyweight
- 5.5 mg/kg	- Corresponding approximately to 0.25 ml per kg
- 11 mg/kg	- Corresponding approximately to 0.5 ml per kg

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

A 3 ml graduated syringe is provided to facilitate the administration of the veterinary medicinal product.

The solution is flavoured. The solution can be administered directly into the mouth of the animal or added to a small quantity of food.

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

No adverse effects have been reported in dogs after administration of high dosage up to 300 mg/kg clindamycin.
Vomiting, loss of appetite, diarrhoea, leukocytosis and elevated liver enzymes have been observed occasionally. In such cases, discontinue the treatment and administer a 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

Clindamycin is mainly a bacteriostatic antibiotic belonging to the group of lincosamides. Clindamycin is a chlorinated analogue of lincomycin. It works by inhibiting bacterial protein synthesis. The reversible coupling to the sub-unit 50-S bacterial ribosome inhibits translation of amino acids linked to the tRNA, thereby preventing elongation of the peptide chain. That is why the mode of action of clindamycin is predominantly bacteriostatic.
Clindamycin and lincomycin have cross-resistance, which is also common between erythromycin and other macrolides.
Acquired resistance can occur, by methylation of the ribosomal binding site via chromosomal mutation in gram positive organisms, or by plasmid-mediated mechanisms in gram negative organisms
Clindamycin is active *in vitro* against many Gram-positive bacteria, Gram positive and Gram-negative anaerobic bacteria. Most aerobic Gram-negative bacteria are resistant to clindamycin.
"CLSI clindamycin veterinary breakpoints are available for dogs in Staphylococcus spp. and Streptococci-ß-haemolytic group in skin and soft tissue infections: S ≤0.5µg/ml; I=1-2µg/ml; R ≥ 4µg/ml". (CLSI July 2013).

The incidence of resistance to lincosamides in *Staphylococcus spp*. appears to be wide-ranging in Europe. Literature data (2016) report an incidence between 25 to 40%.

4.3 Pharmacokinetics

Clindamycin is almost completely absorbed after oral administration. After oral administration of 11mg/kg, maximum plasma concentrations of 8µg/ml are reached within one hour (without any influence of food).
Clindamycin is widely distributed and may concentrate in some tissues.
Elimination half life of clindamycin is around 4 hours. Approximately 70% is excreted in faeces and 30% in the urine.
Clindamycin is approximately 93% bound to plasma proteins.

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 product.

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

Do not store above 30ºC.

5.4 Nature and composition of immediate packaging

A cardboard box containing:

- a 20 mL amber translucent multidose bottle made in glass material (type III),
- a childproof white cap equipped with an inviolability ring, made in high density polyethylene ; fitted with a transparent low density polyethylene part inside (insert)
- a 3 mL syringe for oral use equipped with a tip cannula (transparent natural barrel made of polypropylene and white plunger made of high density polyethylene material)

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any 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

Date of first authorisation: {DD/MM/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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 1 bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zodon 25 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Clindamycin 25,0 mg
(equivalent to 27,15 mg clindamycin hydrochloride)

3. PACKAGE SIZE

20 mL and 3 mL syringe

4. TARGET SPECIES

Cats and dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIOD

8. EXPIRY DATE

Exp.{mm/yyyy}
Once opened, use within 28 days.
Once opened, use by….

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30ºC

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 PACKAGE UNITS
Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zodon

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Clindamycin 25,0 mg/ml
(equivalent to clindamycin hydrochloride 27,15 mg/ml)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 28 days.
Once opened, use by….

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Zodon 25 mg/ml oral solution for cats and dogs

2. Composition

Each ml contains:
Active substance:
Clindamycin 25,0 mg
(equivalent to 27,15 mg clindamycin hydrochloride)

Excipients:
Ethanol 96% (E1510) 72 mg

Clear, amber solution.

3. Target species

Cats and Dogs.

4. Indications for use

Cats:
For the treatment of infected wounds and abscesses caused by clindamycin- susceptible species of *Staphylococcus spp* and *Streptococcus spp*.

Dogs:
- For the treatment of infected wounds, abscesses and oral cavity/dental infections caused by or associated with clindamycin-sensitive species of *Staphylococcus spp*, *Streptococcus spp*, *Bacteroides spp*, *Fusobacterium necrophorum*, *Clostridium perfringens*
- Adjunctive treatment of mechanical or surgical periodontal therapy in the treatment of infections of the gingival and periodontal tissues
- For the treatment of osteomyelitis caused by *Staphylococcus aureus*

5. Contraindications

Do not use in hamsters, guinea pigs, rabbits, chinchillas, horses or ruminants because clindamycin ingestion by these species may cause severe gastrointestinal disorders.
Do not use in cases of hypersensitivity to the active substances, to lincomycin or to any of the excipients.

6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:

Inappropriate use of the product may increase the prevalence of bacteria resistant to clindamycin. Whenever possible, clindamycin should only be used based on susceptibility testing including the D-zone test.

Official national and local antimicrobial policies should be taken into account when the product is used. Clindamycin is likely to favour the proliferation of non-susceptible organisms such as resistant *Clostridia spp* and yeasts. In case of secondary infection, appropriate corrective measures should be taken based on clinical observations.
Clindamycin shows parallel-resistance with lincomycin and co-resistance with erythromycin. There is a partial cross-resistance to erythromycin and other macrolides.
In case of administration of high doses of clindamycin or during prolonged therapy of one month or greater, tests for liver and renal functions and blood counts should be performed periodically
In dogs and cats with kidney problems and/or liver problems, accompanied by severe metabolic aberrations, the dose to be administered should be carefully determined and their condition should be monitored by performing appropriate blood tests during treatment.
The use of the product is not recommended in neonates.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands carefully after use.
People with known hypersensitivity to lincosamides (clindamycin and lincomycin) should avoid contact with the veterinary medicinal product.
Care should be taken to avoid accidental ingestion as this may result in gastro-intestinal effects such as abdominal pain and diarrhoea.
In case of accidental ingestion, particularly by a child, or allergic reaction seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
While high dose studies in rats suggests that clindamycin is not a teratogen and does not significantly affect the breeding performance of males and females, the safety of the veterinary medicinal product in pregnant bitches/queens or breeding male dogs/cats has not been established.
Use only according to the benefit/risk assessment by the responsible veterinarian.
Clindamycin can pass the placenta and blood-milk barrier. As a consequence, treatment of lactating females can cause diarrhoea in puppies and kittens.

Interaction with other medicinal products and other forms of interaction:
- Aluminium salts and hydroxides, kaolin and Aluminium-Magnesium-Silicate complex may reduce the gastrointestinal absorption of lincosamides. Products containing these substances should be administered at least 2 hours before clindamycin.
- Cyclosporin: clindamycin may reduce levels of this immunosuppressive drug with a risk of lack of activity.
- Neuro-muscular blocking agents: Clindamycin possesses intrinsic neuromuscular blocking activity and should be used cautiously with other neuromuscular blocking agents (curares). Clindamycin may increase neuromuscular blockade.
- Do not use clindamycin simultaneously with chloramphenicol or macrolides as they both target the ribosome 50S subunit and antagonist effects may develop.
- When using clindamycin and aminoglycosides (e.g. gentamicin) simultaneously, the risk of adverse interactions (as acute renal failure) cannot be excluded.

Overdose :

No adverse effects have been reported in dogs after administration of high dosage up to 300 mg/kg clindamycin.
Vomiting, loss of appetite, diarrhoea, leukocytosis and elevated liver enzymes have been observed occasionally. In such cases, discontinue the treatment and administer a symptomatic treatment.

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

7. Adverse events

Cats, dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Vomiting, Diarrhoea

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.

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

Orale use :

Recommended dose:

Cats:

- Infected wounds, abscesses: 11mg of clindamycin per kg of body weight per 24h or 5.5 mg /kg per 12h for 7 to 10 days.

The treatment should be stopped if no therapeutic effect is observed after 4 days.

Dogs:

- Infected wounds, abscesses and oral cavity/dental infections: 11 mg clindamycin per kg of body weight per 24h or 5.5 mg /kg per 12h for 7 to 10 days.

The treatment should be stopped if no therapeutic effect is observed after 4 days.

- Treatment of bone infections (osteomyelitis): 11 mg clindamycin per kg of body weight every 12 hours for a period of 28 days minimum. The treatment should be discontinued if no therapeutic effect is observed in the first 14 days.

Dosage	Volume to be administered per kg bodyweight
5.5 mg/kg	Corresponding approximately to 0.25 ml per kg
11 mg/kg	Corresponding approximately to 0.5 ml per kg

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

9. Advice on correct administration

A 3 ml graduated syringe is provided to facilitate the administration of the veterinary medicinal product.

The solution is flavoured. The solution can be administered directly into the mouth of the animal or added to a small quantity of food.

10. Withdrawal period

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30ºC
Shelf life after first opening the immediate packaging: 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 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

(MA)

Pack sizes:
A cardboard box containing:
- a 20 mL multidose bottle
- a 3 mL syringe

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
(Name and address to be completed nationally)
Tel: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:

Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 Louverné
France

Laboratoires Biové
3 Rue de Lorraine
62510 Arques
France

Ceva Santé Animale
Zone industrielle Très Le bois
22600 Loudéac
France

17. Other information