A. LABELLING

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zodon 25 mg/ml oral solution for cats and dogs
clindamycin hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Clindamycin 25,0 mg
(equivalent to 27,15 mg clindamycin hydrochloride)
Excipients:
Ethanol 96% (E1510) 72 mg

3. PHARMACEUTICAL FORM

Oral solution
Clear, amber solution

4. PACKAGE SIZE

20 mL including 3 mL syringe

5. TARGET SPECIES

Cats and dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened, use by …
Shelf-life after first opening the container: 28 days

11. SPECIAL STORAGE CONDITIONS

Do not store above 30^{o}C

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4125

17. MANUFACTURER'S BATCH NUMBER

Batch:

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zodon 25 mg/ml oral solution for cats and dogs
clindamycin hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTE(S) OF ADMINISTRATION

Oral route

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch number

7. EXPIRY DATE

EXP {month/year}
Once opened, use by …
Shelf-life after first opening the container: 28 days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

ZODON 25 MG/ML ORAL SOLUTION FOR CATS AND DOGS
clindamycin hydrochloride

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zodon 25 mg/ml oral solution for cats and dogs
clindamycin (as hydrochloride)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

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

Excipients:
Ethanol 96% (E1510) 72 mg

Clear, amber oral solution.

4. INDICATION(S)

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 either clindamycin or lincomycin, or to any of the excipients

6. ADVERSE REACTIONS

Vomiting and/or diarrhoea have been very rarely reported.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.
Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

Cats and Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration only

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 30ºC
Once opened use the product within 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.
When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals

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 (symptoms, emergency procedures, 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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

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

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

Approved 19 October 2022