# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zodon 88 mg chewable tablets for dogs
clindamycin (as hydrochloride)

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Clindamycin (as hydrochloride).....88 mg

## 3. PHARMACEUTICAL FORM

Chewable tablet

## 4. PACKAGE SIZE

10 tablets
20 tablets
100 tablets
120 tablets
240 tablets

## 5. TARGET SPECIES

Dogs

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

Not applicable

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP {month/year}
Once opened use within 72 hours.

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.
Tablet portions should be stored in the blister pack
Keep the blister in the outer carton.

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

Disposal: read package leaflet

## 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 15052/4128

## 17. MANUFACTURER'S BATCH NUMBER

Batch

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

Blister

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zodon 88 mg chewable tablets for dogs
clindamycin (as hydrochloride)

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

## 3. EXPIRY DATE

EXP {month/year}

## 4. BATCH NUMBER

Batch

## 5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

**Veterinary Medicinal product**

# ZODON 88 MG CHEWABLE TABLETS FOR DOGS

**PART IB**

**B – PACKAGE LEAFLET**

**Pharmaceutical form**

Chewable Tablet

# PACKAGE LEAFLET:

# ZODON 88 MG CHEWABLE TABLETS FOR DOGS

## 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 LOUVERNE
FRANCE

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zodon 88 mg chewable tablets for dogs
clindamycin (as hydrochloride)

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

Each tablet contains
**Active substance:**
Clindamycin (as hydrochloride) .....88 mg
Chewable tablet
Clover-shaped scored beige tablet. The tablet can be divided into four equal parts

## 4. INDICATION(S)

- 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.*
- For the treatment of superficial pyoderma associated with *Staphylococcus pseudintermedius.*
- For the treatment of osteomyelitis, cau*sed by Staphylococcus aureus.*

## 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 or ruminants. because ingestion of clindamycin by these species may result in severe gastro-intestinal disturbance.

## 6. ADVERSE REACTIONS

Vomiting and diarrhoea have been reported very rarely.
Hypersensitivity reactions and thrombocytopenia have been reported very rarely.

Clindamycin sometimes causes the overgrowth of non-sensitive organisms such as clostridia and yeasts. In cases of superinfection, appropriate measures must be taken according to the clinical situation.
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 serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.
Alternatively, you can report via your national reporting system {national system details}.

## 7. TARGET SPECIES

Dogs

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

For oral administration.

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

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

3. For the treatment of osteomyelitis in dogs, administer:
   - 11 mg/kg of 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.
For example:

- For a dose regimen of 11mg/kg

| Weight (kg) | Number of tablets per administration |
|---|---|
| 1.0 – 2.0 | ¼ tab |
| 2.1 – 4.0 | ½ tab |
| 4.1 – 6.0 | ¾ tab |
| 6.1 – 8.0 | 1 tab |
| 8.1 – 10.0 | 1 + ¼ tabs |
| 10.1 – 12.0 | 1 + ½ tabs |
| 12.1 – 14.0 | 1 + ¾ tabs |
| 14.1 – 16.0 | 2 tabs |

- For a dose regimen of 5.5 mg/kg

| Weight (kg) | Number of tablets per administration |
|---|---|
| 2.0 – 4.0 | ¼ tab |
| 4.1 – 8.0 | ½ tab |
| 8.1 – 12.0 | ¾ tabs |
| 12.1 – 16.0 | 1 tab |

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

## 9. ADVICE ON CORRECT ADMINISTRATION

The tablets are flavoured. They can be administered directly into the mouth of the animals or with a small quantity of food.
Instruction on how to divide the tablet: Put the tablet on an even surface, with its scored side facing down (convex face up). With the tip of the forefinger, exert slight vertical pressure on the middle of the tablet to break it along its width into halves. Then, in order to obtain quarters, exert slight pressure on the middle of one half with the forefinger to break it into two parts.

## 10. WITHDRAWAL PERIOD

Not applicable

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 30°C.
Tablet portions should be stored in the blister pack.
Shelf life for tablet portions after first opening the immediate packaging: 72 hours (or 3 days)
Keep the blister in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after {EXP}. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals:
The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal.
Official and local antimicrobial policies should be taken into account when the product is used.
Use of the 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 antimicrobials due to the potential for cross-resistance

Clindamycin and erythromycin show parallel resistance. Partial cross-resistance has been demonstrated between clindamycin, erythromycin and other macrolide antibiotics.
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to lincosamides (lincomycin and clindamycin) 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 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 diarrhoea in puppies.
Use the product only according to the benefit/risk assessment by the responsible veterinarian.
The use of the product is not recommended in neonates.

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 product should be used with caution in animals receiving such agents.

Clindamycin should not be combined with erythromycin or other macrolides to prevent macrolide-induced resistance to clindamycin.
Clindamycin may reduce plasma levels of cyclosporin with a risk of lack of activity.

During the simultaneous use of clindamycin and aminoglycosides (eg gentamicin), the risk of adverse interactions (acute renal failure) cannot be excluded**.**

Overdose (symptoms, emergency procedures, antidotes):
In dogs, 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.

## 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 products should be disposed of in accordance with local requirements

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

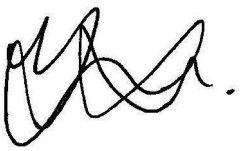
October 2022

## 15. OTHER INFORMATION

Pack sizes:
Cardboard box with 10 tablets
Cardboard box with 20 tablets
Cardboard box with 100 tablets
Cardboard box with 120 tablets
Cardboard box with 240 tablets

Not all pack sizes may be marketed.

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



Approved: 18 October 2022