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 for dogs
clindamycin

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Tablets

4. 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

5. TARGET SPECIES

Dogs

6. INDICATION

7. METHOD AND ROUTE OF ADMINISTRATION

For oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf life of divided tablets: 3 days.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL 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

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50406/4005

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Aluminium-Polyamide/Aluminium/PVC **blisters**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindabactin 220 mg chewable tablets
clindamycin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Clindabactin 220 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:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:
LelyPharma B.V.
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindabactin 220 mg chewable tablets for dogs
clindamycin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

1 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.

4. INDICATIONS

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. ADVERSE REACTIONS

Vomiting and diarrhoea have been observed uncommonly.

Clindamycin uncommonly causes the 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.

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

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE 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/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 , administer either:

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

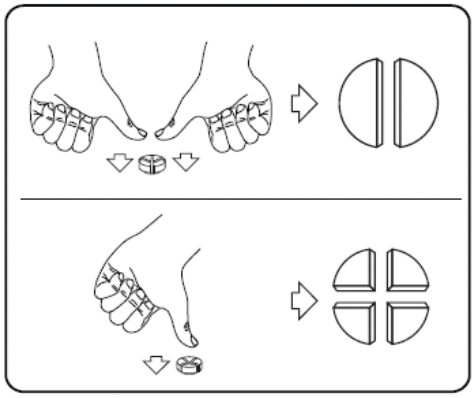
Therapy of canine superficial pyoderma is usually recommended for 21 days, with shortening or extension of therapy based on clinical judgement.

3. For the treatment of osteomyelitis , administer:
• 11 mg/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.
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 PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Shelf life of divided tablets after first opening the immediate packaging: 3 days.
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 package after EXP.
The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

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. If this is not possible, therapy should be based on local epidemiological information about susceptibility of the target bacteria.

Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Use of the 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 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 diarrhoea 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 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 (symptoms, emergency procedures, 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.

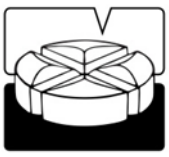
13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. 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

15. OTHER INFORMATION

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.



Divisible tablet

Approved: 05 September 2023