LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{NATURE/TYPE} Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindaseptin 25mg capsules for dogs
Clindamycin

2. STATEMENT OF ACTIVE SUBSTANCES

Active Ingredient

Each capsule contains: Clindamycin (as Clindamycin Hydrochloride) 25.0 mg

3. PHARMACEUTICAL FORM

Capsule

4. PACKAGE SIZE

Package size:

2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80 , 82, 84, 86, 88, 90, 92, 94, 96, 98, 100, 112, 120, 128, 130, 140, 150, 154, 160, 168, 180, 182, 186, 190, 196, 200, 210, 224, 240, 250, 252, 256, 260, 266, 270, 280, 290, 294, 300, 308, 320, 350, 390, 392, 448, 500, 450, 540, 546, 600, 602, 700, 750, 800, 798, 810, 896, 900, 994 and 1000 Capsules

5. TARGET SPECIES

Dogs

6. INDICATION(S)

The product is indicated for the treatment of infected wounds, abscesses, superficial pyoderma and oral cavity/dental infections caused by or associated with clindamycin-sensitive staphylococci, streptococci, bacteroidaceae, *Fusobacterium necrophorum*, *Clostridium perfringens* and osteomyelitis caused by *Staphylococcus aureus*. The product can also be used to help provide antimicrobial cover during dental procedures.

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}>

11. SPECIAL STORAGE CONDITIONS

Keep container in outer carton.

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

Any unused product or waste material should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY"

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

MA Holder: Chanelle Animal Health, 7 Rodney Street, Liverpool L1 9HZ, UK

16. MARKETING AUTHORISATION NUMBER

Vm 11990/4059

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

POM-V

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindaseptin 25mg capsules for dogs
Clindamycin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd.

3. EXPIRY DATE

<EXP {month/year}>

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
CLINDASEPTIN 25mg CAPSULES 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:
Chanelle Animal Health Ltd., 7 Rodney Street, Liverpool L1 9HZ, United Kingdom

Manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLINDASEPTIN 25 mg CAPSULES FOR DOGS

Clindamycin

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

Active substance:	mg per capsule
Clindamycin. (as clindamycin hydrochloride)	25.0
Excipients:	
Capsule shell	
Red Iron Oxide (E172)	0.57
Titanium Dioxide (E171)	0.19

4. INDICATION(S)

The product is indicated for the treatment of infected wounds, abscesses, superficial pyoderma and oral cavity/dental infections caused by or associated with clindamycin-sensitive staphylococci, streptococci, bacteroidaceae, *Fusobacterium necrophorum*, *Clostridium perfringens* and osteomyelitis caused by *Staphylococcus aureus*. The product can also be used to help provide antimicrobial cover during dental procedures.

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to clindamycin, lincomycin or to any of the excipients.

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

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon. Vomiting and diarrhoea are observed occasionally. Clindamycin sometimes causes the overgrowth of non sensitive organisms such as resistant *Clostridia* and yeasts. In cases of superinfection, appropriate measures should be taken according to the clinical situation.

7. TARGET SPECIES

Dogs

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

For oral administration.

For treatment of infected wounds, abscesses, oral cavity/dental infections, administer 5.5 mg/kg bodyweight every 12 hours for 7 - 10 days (i.e. 1 capsule per 4.5 kg bodyweight twice daily). Treatment may be extended to a maximum of 28 days based on clinical judgement. If no improvement is seen within 4 days, the sensitivity of the pathogens involved should be redetermined.

For the treatment of superficial pyoderma administer 11 mg/kg every 24 hours (i.e. 2 capsules per 4.5 kg bodyweight once daily). Continue treatment for at least 21 days.

For the treatment of osteomyelitis administer 11 mg/kg every 12 hours (i.e. 2 capsules per 4.5 kg bodyweight twice daily) for at least 28 days. If no improvement is seen within 14 days, the sensitivity of the pathogens involved should be redetermined.

To help provide antimicrobial cover during dental procedures, a 10 day course of 5.5 mg/kg every 12 hours is recommended (i.e. 1 capsule per 4.5 kg twice a day beginning 5 days before the intended procedure and continuing for 5 days thereafter).

The minimum bodyweight to be treated is 4.5 kg.

9. ADVICE ON CORRECT ADMINISTRATION

For animal treatment only.

10. WITHDRAWAL PERIOD

Not Applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the containers in the outer carton.

This veterinary medicinal product does not require any special storage conditions.

Do not use after the expiry date stated on the label and carton after EXP

12. SPECIAL WARNING(S)

Special warnings for each target species

Before use of Clindaseptin capsules, the identification of causative pathogenic micro-organisms should be carried out and their susceptibility to clindamycin should be established.

Special precautions for use in animals

The bioavailability of the product is higher in fasting dogs compared to non-fasting dogs.

During prolonged therapy of one month or greater periodic liver and kidney function tests and blood counts should be performed. Patients with severe renal and/or hepatic disturbances accompanied by severe metabolic aberrations should be dosed with caution and should be monitored by serum examination during clindamycin therapy.

Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing. 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 this package leaflet 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 macrolides antibiotics.

User warnings

Those with known hypersensitivity to lincosamides (lincomycin, clindamycin) should not handle the product. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the Doctor this warning. Swelling of the face, lips or eyes, or breathing difficulties are more serious symptoms and require urgent medical attention.

Accidental ingestion of this product may cause transient gastrointestinal effects, and so should be avoided. If a child accidentally consumes this product, seek medical advice.

Pregnancy, lactation and fertility

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, safety during pregnancy and lactation or in breeding male dogs has not been established. Clindamycin crosses the placental and blood-milk barriers. Treatment of lactating females can cause diarrhoea in puppies. Therefore, the administration of the veterinary medicinal product during pregnancy and lactation should be the subject of a benefit/risk assessment by the veterinarian.

Interaction with other medicaments and other forms of interaction:

Neuromuscular blocking effects have been observed with clindamycin possibly leading to an increase of efficacy of other neuromuscular blocking agents. The concomitant use of such drugs must be handled with care.

Clindamycin should not be used concomitantly with chloramphenicol or macrolides because they may antagonise each other at the site of action.

Clindamycin may reduce plasma levels of cyclosporin 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.

Overdose

Symptoms of overdose include vomiting, inappetency and diarrhoea. In such cases, treatment should be stopped immediately and the dogs treated symptomatically.

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

Any unused product or waste material should be disposed of in accordance with local requirements. Medicines should not be disposed of via waste water or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package sizes:

2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80 , 82, 84, 86, 88, 90, 92, 94, 96, 98, 100, 112, 120, 128, 130, 140, 150, 154, 160, 168, 180, 182, 186, 190, 196, 200, 210, 224, 240, 250, 252, 256, 260, 266, 270, 280, 290, 294, 300, 308, 320, 350, 390, 392, 448, 500, 450, 540, 546, 600, 602, 700, 750, 800, 798, 810, 896, 900, 994 and 1000 Capsules

Not all pack sizes may be marketed

POM-V Prescription Only Medicine

Approved: 25 July 2019