

**PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND>
<IMMEDIATE PACKAGE>**

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clinacin 300mg Tablets for Dogs

Clindamycin hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 300 mg Clindamycin (as Clindamycin Hydrochloride)

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

Container: 6, 10, 14, 16, 20, 28, 30, 42, 50, 56, 60, 70, 80, 84, 98, 100 and 200 tablets.
Blisters: 6, 10, 14, 20, 28, 30, 42, 50, 56, 60, 70, 84, 98, 100, 140, 180, 200, 250,
280, 300, 500 and 1000 tablets.

5. TARGET SPECIES

Dogs

6. INDICATION(S)

CLINACIN 300 mg TABLETS are indicated for use in dogs for the treatment of infected wounds, abscesses, oral cavity/dental infections and to help provide antimicrobial cover during dental procedures at a dose-rate of 5.5 mg/kg clindamycin every 12 hours.

CLINACIN 300 mg TABLETS are also indicated for the treatment of superficial pyoderma in dogs at a dose-rate of 11 mg/kg every 24 hours.

CLINACIN 300 MG TABLETS can also be used for the treatment of osteomyelitis at a dose-rate of 11 mg/kg every 12 hours.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

The tablets can be divided into halves or quarters.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

See Package Leaflet for full details of dosage, contra-indications, warnings etc.

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.
Return any divided tablets to the blister pack or container and use within 72 hours.
Divided tablets should be used at the next administration.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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
[Distribution category]

POM-V

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

Chanelle Animal Health Ltd., 7 Rodney Street, Liverpool L1 9HZ, UK.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 11990/4053

17. MANUFACTURER’S BATCH NUMBER

B. PACKAGE LEAFLET

**PACKAGE LEAFLET
CLINACIN 300mg 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:
Chanelle Animal Health Ltd., 7 Rodney Street, Liverpool L1 9HZ, United Kingdom.

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clinacin 300 mg Tablets for Dogs
Clindamycin Hydrochloride

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

Clinacin 300mg Tablets contain 300mg of the active ingredient Clindamycin (as Clindamycin Hydrochloride).

Each tablet also contains the following inactive ingredients: Ludipress (Lactose Monohydrate, Povidone and Crospovidone), Microcrystalline Cellulose, Sodium lauryl sulphate, Colloidal silicon dioxide, Magnesium stearate, Grilled meat flavour.

The tablet is plain white to off white tablet with a cross break line on one side.
The tablets can be divided into halves or quarters.

4. INDICATION(S)

Clinacin 300 mg Tablets are indicated for use in dogs 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*. Clinacin 300mg tablets can also be used to help provide antimicrobial cover during dental procedures.

5. CONTRAINDICATIONS

CLINACIN TABLETS are contra-indicated in animals hypersensitive to clindamycin or lincomycin preparations. Do not administer to rabbits, guinea pigs, chinchillas, hamsters, horses or ruminants. Clindamycin should not be used concomitantly with chloramphenicol or macrolides as they may antagonise each other at their site of action.

6. ADVERSE REACTIONS

Clindamycin sometimes 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. Vomiting and diarrhoea have occasionally been observed.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

For oral administration.

Dental infections, wounds and abscesses

For treatment of infected wounds, abscesses, oral cavity/dental infections, administer 5.5 mg/kg bodyweight every 12 hours for 7 - 10 days. 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 re-determined. To help provide antimicrobial cover during dental procedures, a 10 day course of 5.5 mg/kg bodyweight every 12 hours is recommended. This should be initiated five days before the intended dental procedure and continued for five days thereafter.

Superficial pyoderma:

For the treatment of superficial pyoderma administer 11 mg/kg every 24 hours. Continue treatment for at least 21 days.

Osteomyelitis:

For the treatment of osteomyelitis administer 11 mg/kg every 12 hours for at least 28 days. If no improvement is seen within 14 days, the sensitivity of the pathogens involved should be re-determined.

Dosage table			
Where stated in the dosing table, use the tablet strength indicated.			
Bodyweight	Dental infections, wounds, abscesses	Superficial pyoderma	Osteomyelitis
	5.5 mg/kg twice daily	11 mg/kg once daily	11 mg/kg twice daily
4.5 kg	1 x 25 mg twice daily	2 x 25 mg once daily	2 x 25 mg twice daily
13.5 kg	1 x 75 mg twice daily	1 x 150 mg once daily	1 x 150 mg twice daily
27.0 kg	1 x 150 mg twice daily	1 x 300 mg once daily	1 x 300 mg twice daily
54.0 kg	1 x 300 mg twice daily	2 x 300 mg once daily	2 x 300 mg twice daily

Tablets can be divided into halves or quarters to ensure accurate dosing. To break a cross scored tablet into quarters, place the tablet on an even surface with the scored side up and apply pressure on the middle with your thumb.



To break a tablet into two halves, place the tablet on an even surface with the scored side up, hold one half of the tablet and press down on the other half.



9. ADVICE ON CORRECT ADMINISTRATION

Return any divided tablets to the blister pack or container and use within 72 hours. Divided tablets should be used at the next administration. Any divided tablets remaining after the last administration of the product should be discarded.

10. WITHDRAWAL PERIOD(S)

Not Applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

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

Return any divided tablets to the blister pack or container and use within 72 hours.

Divided tablets should be used at the next administration.

12. SPECIAL WARNING(S)

Clindamycin and lincomycin show parallel resistance.

Partial cross-resistance has been demonstrated between clindamycin, erythromycin and other macrolide antibiotics. Before use of Clinacin tablets, the identification of causative pathogenic micro-organisms should be carried out and their susceptibility to clindamycin should be established.

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. CLINACIN TABLETS should be used with caution in animals receiving such agents.

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 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.

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. Therefore, the administration of the veterinary medicinal product during pregnancy and lactation should be the subject of a benefit/risk assessment by the veterinarian.

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

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

For Animal Treatment Only

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

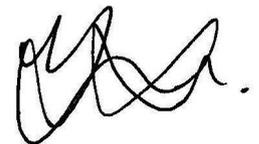
September 2020

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription
Vm 11990/4053

Clinacin 300mg Tablets are presented in either white high density polyethylene bottle with child resistant tamper evident polypropylene closure, containing 6, 10, 14, 16, 20, 28, 30, 42, 50, 56, 60, 70, 80, 84, 98, 100 and 200 tablets or blister (45um soft temper aluminium/ 30um hard temper aluminium) containing 6, 10, 14, 20, 28, 30, 42, 50, 56, 60, 70, 84, 98, 100, 140, 180, 200, 250, 280, 300, 500 and 1000 tablets

Not all pack sizes may be marketed.



Approved: 30 September 2020