PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clinacin 25 mg tablets for dogs

Clindamycin hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 25 mg Clindamycin (as clindamycin hydrochloride)

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

100 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Clinacin 25 mg Tablets are indicated in dogs for the treatment of infected wounds, abscesses, and oral cavity/dental infections and to help provide antimicrobial cover during dental procedures at a dose rate of 5.5 mg/kg every 12 hours.

Clinacin 25 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 25 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

See package leaflet for full details of dosage, contraindications, warnings etc.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Store in the original container

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

See package leaflet

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

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 REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Limited

7 Rodney Street

Liverpool L1 9HZ

United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 11990/4025

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

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

Chanelle Animal Health Limited, 7 Rodney Street' Liverpool. L1 9HZ. United Kingdom

Manufacturer:

Chanelle Pharmaceuticals Manufacturing Ltd, Loughrea, Co, Galway, Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clinacin 25 mg tablets for dogs

Clindamycin hydrochloride

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

Clinacin 25 mg tablets contain 25 mg 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.

4. INDICATION(S)

Clinacin tablets are indicated for use in dogs for the treatment of infected wounds, abcesses, oral cavity infections and to help provide antimicrobial cover during dental procedures. These tablets are also indicated for the treatment of superficial pyoderma and osteomyelitis.

5. CONTRAINDICATIONS

Clinacin tablets are contraindicated in animals hypersensitive to clindamycin and lincomycin preparations. Do not administer to rabbits, guinea pigs, chinchillas, hamsters, horses or ruminants. Clindamycin should not be used concurrently 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 should be taken according to the clinical situation.

Vomiting and diarrhoea are observed occasionally.

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.

Bodyweight	**Dental infections, wounds, abscesses** 5.5mg/kg twice daily	**Superficial pyoderma** 11 mg/kg once daily	**Osteomyelitis** 11 mg/kg twice daily
Up to 2.25 kg	Half a 25 mg twice daily	1 x 25 mg once daily	1 x 25 mg twice daily
2.25 – 4.5 kg	1 x 25 mg twice daily	2 x 25 mg once daily	2 x 25 mg twice daily
4.6 – 9.0 kg	2 x 25 twice daily	4 x 25 mg once daily	4 x 25 mg twice daily
9.1 – 13.5 kg	1 x 75 mg twice daily	1 x 150 mg once daily	1 x 150 mg twice daily
13.6 – 18.0 kg	1 x75 mg and 1 x 25 mg twice daily	1 x 150 mg and 2 x 25 mg once daily	1 x 150 mg and 2 x 25 mg twice daily
18.1 – 27.0	1 x 150 mg twice daily	2 x 15 mg once daily	2 x 150 mg twice daily
Over 27 kg	2 x 150 mg twice daily	4 x 150 mg once daily	4 x 150 mg twice daily

For treatment of infected wounds, abscesses, oral cavity/dental infections, administer 5.5 mg/kg bodyweight every 12 hours for 7 – 10. 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.

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

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.

To help provide antimicrobial cover during dental procedures, a 10 day course of 5.5 mg/kg every 12 hours is recommended. This should be initiated five days before the intended dental procedure and continued five days thereafter.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

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

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

12. SPECIAL WARNING(S)

Clindamycin and lincomycin show parallel resistance.

Partial cross resistance has been demonstrated between clindamycin, erythromycin and other macrolide antibiotics.

Before the use of Clinacin tablets the identification of causative pathogenic micro-organisms should be carried out and their susceptibility to clindamysin should be established.

Clindamycin has shown to hove 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 function tests and blood counts should be performed. Patients with severe renal and/or very severe hepatic disturbances accompanied by severe metabolic abberations should be

dosed with caution and should be monitored by serum examination during high dose clindamycin therapy.

While high doses 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 dogs has not been established.

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

Dispose of used packaging in the household waste. Unused product should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM - V

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Approved: 30/01/2018