<PARTICULARS TO APPEAR ON THE OUTER PACKAGE> Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindaseptin 300mg capsules for dogs

Clindamycin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active Ingredient

Each capsule contains: Clindamycin (as Clindamycin Hydrochloride) 300.0 mg

3. PHARMACEUTICAL FORM

Capsule, hard

4. PACKAGE SIZE

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 and 1000 Capsules

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

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

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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.

POM-V

Prescription Only Medicine-Veterinarian

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

Distributor: Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr Alderton, Towcester, Northants, NN12 7LS

16. MARKETING AUTHORISATION NUMBER

VM 11990/4058

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindaseptin 300mg 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.

PACKAGE LEAFLET

CLINDASEPTIN 75 mg CAPSULES For Dogs
CLINDASEPTIN 150 mg CAPSULES For Dogs
CLINDASEPTIN 300 mg 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 for the batch release: Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.

Distributor:
Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton, Towcester
Northants
NN12 7LS

2. NAME OF THE VETERINARY MEDICINAL PRODUCTS

Clindaseptin 75 mg capsules for dogs
Clindaseptin 150 mg capsules for dogs
Clinadseptin 300 mg capsules for dogs
Clindamycin

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

Clindaseptin 75mg, 150mg and 300mg Capsules contain 75mg, 150mg and 300mg (respectively) of the active ingredient Clindamycin (as Clindamycin Hydrochloride).

The 75mg capsule consists of a lavender body (Azorubine E122 and Indigo carmine FD&C Blue2 E132) and a lavender cap (Azorubine E122 and Indigo carmine FD&C Blue 2 E132 with iron oxide black (E172) and titanium dioxide (E171)).

The 150mg capsule consists of a lavender body (Azorubine (E122) and Indigo carmine FD&C blue 2 (E132)) and a maroon cap (Azorubine (E122), Indigo carmine FD&C blue 2 (E132) and titanium dioxide (E171) with iron oxide black (E172) and titanium dioxide (E171)).

The 300mg capsule consists of a blue body (Patent Blue V (E131) and titanium dioxide (E171)) and a blue cap (Patent Blue V (E131) and titanium dioxide (E171)).

4. INDICATION(S)

The product is 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. The capsules are also indicated for the treatment of superficial pyoderma and osteomyelitis.

5. CONTRAINDICATIONS

The product is contra-indicated in animals hypersensitive to clindamycin or to any of the excipients or to lincomycin preparations.

Do not administer to rabbits, guinea pigs, chinchillas, hamsters, horses or ruminants because ingestion of clindamycin by these species may result in severe gastro-intestinal disturbance.

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.

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.

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 bodyweight every 12 hours is recommended. This should be initiated five days before the intended dental procedure and continued for five days thereafter.

Dosage table

Bodyweight	**Dental infections, wounds, abscesses**	**Superficial derma**	**Osteomyelitis**
	5.5 mg/kg twice daily	**11 mg/kg once daily**	**11 mg/kg 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 150mg twice daily	1 x 300 mg once daily	1 x 300 mg twice daily
54.0 kg	1 x 150 mg twice daily	1 x 300 mg once daily	1 x 300 mg twice daily

9. ADVICE ON CORRECT ADMINISTRATION

See section 8.

10. WITHDRAWAL PERIODS

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. The expiry date refers to the last day of that month.

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 Clindaseptin capsules, the identification of causative pathogenic micro-organisms should be carried out and their susceptibility to clindamycin should be established. Use of the product is not recommended in suckling puppies (see section 4.7). 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 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 macrolides antibiotics.

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

Clindamycin 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 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.
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. Clindamycin crosses the placental and blood-milk barriers. Treatment of lactating females can cause diarrhoea in puppies.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In persons hypersensitive (allergic) to lincosamides (lincomycin, clindamycin), this product can, in serious cases, cause swelling of the face, lips and eyes, or breathing difficulties.
Those with known hypersensitivity to lincosamides should not handle the product.
Accidental ingestion of this product may cause transient gastrointestinal effects, and so should be avoided.
If you develop symptoms following exposure or in case of accidental ingestion, particularly by children, seek medical advice immediately and show the package leaflet or the label to the physician.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2013

15. OTHER INFORMATION

Capsules are presented as 2, 4, 6, 8 or 10 per strip.

Carton with blister strips of: 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, 450, 500, 540, 546, 600, 602, 700, 750, 800, 798, 810, 896, 900 and 1000 capsules

Not all pack sizes may be marketed.

For animal treatment only.

POM-V

To be supplied only on veterinary prescription

Approved: 14 August 2018