

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Clindacyl 300mg Tablets for dogs

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each tablet contains 300 mg Clindamycin (as Clindamycin Hydrochloride)

**3. PHARMACEUTICAL FORM**

Antibiotic tablet.

**4. PACKAGE SIZE**

300 mg

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) 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.

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.

To help provide antimicrobial cover during dental procedures, a 10 day course of 5.5 mg/kg every 12 hours is recommended, beginning 5 days before the intended procedure and continuing for 5 days thereafter.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

## **9. SPECIAL WARNING(S), IF NECESSARY**

Do not administer to animals with hypersensitivity to clindamycin or any excipients or to lincomycin preparations.

Do not administer to rabbits, guinea pigs, chinchillas, hamsters, horses or ruminants.

Clindamycin should not be used concomitantly with chloramphenicol or macrolides because they may antagonise each other at the site of action. Symptoms of overdose include vomiting, inappetency and diarrhoea. In such cases, treatment should be stopped immediately and the dogs treated symptomatically. Before the use of Clindacyl 300mg tablets, the identification of causative pathogenic micro-organisms should be carried out and the sensitivity to clindamycin should be established. Clindamycin and lincomycin show parallel resistance. There is a partial cross-resistance to erythromycin and other macrolide antibiotics.

Reaad the package leaflet before use.

## **10. EXPIRY DATE**

## **11. SPECIAL STORAGE CONDITIONS**

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

Keep the container in the outer carton.

## **12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

## **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]**

POM-V

To be supplied only on veterinary prescription.

For animal treatment only

## **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**

Vetoquinol UK Limited  
Buckingham Industrial Park  
Buckingham  
MK18 1PA

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 08007/4129

**17. MANUFACTURER'S BATCH NUMBER**

Product not Marketed

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Clindacyl 300mg Tablets for dogs

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Each tablet contains clindamycin 300 mg (as Clindamycin Hydrochloride)

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

100 Tablets

**4. ROUTE(S) OF ADMINISTRATION**

For oral administration. Read the package leaflet before use.

**5. WITHDRAWAL PERIOD**

**6. BATCH NUMBER**

**7. EXPIRY DATE**

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only

Product not Marketed

**PACKAGE LEAFLET FOR: Clindacyl Tablets for dogs**

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

Vetoquinol UK Limited  
Vetoquinol House  
Great Slade  
Buckingham Industrial Park  
Buckingham  
MK18 1PA

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Clindacyl Tablets for dogs

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

Clindamycin 300 mg (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)**

Clindacyl Tablets are 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*. Clindacyl Tablets can also be used to help provide antimicrobial cover during dental procedures.

**5. CONTRAINDICATIONS**

Do not administer to animals with hypersensitivity to clindamycin or any excipients or to lincomycin preparations. Do not administer to rabbits, guinea pigs, chinchillas, hamsters, horses or ruminants.

## **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.

## **7. TARGET SPECIES**

Dogs

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF 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 redetermined.

## **9. ADVICE ON CORRECT ADMINISTRATION**

To help provide antimicrobial cover during dental procedures, a 10 day course of 5.5 mg/kg every 12 hours is recommended (see table below), beginning 5 days before the intended procedure and continuing for 5 days thereafter.

Bodyweight	Dental infections Wounds, abscesses	Superficial pyoderma	Osteomyelitis
	5.5mg/kg every 12h	11mg/kg every 24h	11mg/kg every 12h
4.5kg	1 x 25mg twice daily	2 x 25mg once daily	2 x 25mg twice daily
13.5kg	1 x 75mg twice daily	1 x 150mg once daily	1 x 150mg twice daily
27.0kg	1 x 150mg twice daily	1 x 300mg once daily	1 x 300mg twice daily
54.0 kg	1 x 300mg twice daily	2 x 300mg once daily	2 x 300mg twice daily

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

#### 10. WITHDRAWAL PERIOD(S)

#### 11. SPECIAL STORAGE PRECAUTIONS

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

#### 12. SPECIAL WARNING(S)

Before the use of Clindacyl tablets, the identification of causative pathogenic micro-organisms should be carried out and the sensitivity to clindamycin should be established. Clindamycin and lincomycin show parallel resistance. There is a partial cross-resistance to erythromycin and other macrolide antibiotics.

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 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**

**15. OTHER INFORMATION**

POM-V

To be supplied only on veterinary prescription

**Vm 08007/4104**

**Vm 08007/4087**

**Vm 08007/4103**

**Vm 08007/4129**

**Pharmacological Properties:** Anti-infectives for systemic use: Lincosamides.  
ATCvet code: QJ01FF01

**Pharmacodynamic properties:** Clindamycin, a chlorinated analogue of lincomycin, is an antibiotic with bacteriostatic action. Bactericidal actions have also been reported. Clindamycin is primarily a bacteriostatic antibiotic of the lincosamide group, which acts by inhibition of protein synthesis. The antibiotic activity of clindamycin is based on the inhibition of bacterial synthesis. Reversible coupling to the 50 s subunit of the bacterial ribosome inhibits inter alia the translation of tRNA-bound amino acids, thereby preventing elongation of the peptide chain. Because of this, the mode of action of clindamycin is predominantly bacteriostatic. Clindamycin has been shown to have in-vitro activity against the following organisms *Staphylococcus* spp; *Streptococcus* spp; *Bacteroides* spp; *Fusobacterium* spp; *Clostridium* spp. Clindamycin and lincomycin show cross-resistance, which is common also to erythromycin and other macrolide antibiotics. Acquired resistance can occur, by methylation of the ribosomal binding site via chromosomal mutation in gram positive organisms, or by plasmid-mediated mechanisms in gram negative organisms.

**Pharmacokinetic particulars:** Clindamycin is rapidly absorbed; following oral administration up to 90% of the active ingredient is absorbed from the gastrointestinal tract. After a single administration of one tablet to fasting dogs maximum plasma level (C<sub>max</sub>) of 5µg/ml are found compared to 3.4µg/ml in non-fasting dogs. Bioavailability is greater in fasting dogs than fed dogs. Clindamycin crosses the placental barrier and can be detected in milk.

**Shelf life:** Clindacyl 25mg tablets Shelf life 3 years, Clindacyl 75 mg tablets Shelf life 3 years, Clindacyl 150 mg tablets Shelf life 3 years, Clindacyl 300 mg tablets Shelf life 4 years.



**Nature and composition of immediate packaging:** Polyethylene bottle with child resistant tamper evident snap-cap closures containing 100 tablets.

**Use during pregnancy and lactation:** 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 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.

**Interaction with other medicinal products 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.

Approved: 08/05/2018

*J. J. J.*

Product not Marketed