

PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindacyl 25mg Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 25 mg Clindamycin (as Clindamycin Hydrochloride)

3. PHARMACEUTICAL FORM

Antibiotic. Tablet

4. PACKAGE SIZE

100 Tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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 25mg Tablets can also be used to help provide antimicrobial cover during dental procedures.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration. For treatment of injected wounds, abscesses, oral cavity/dental infections, administer 5.5 mg/kg bodyweight every 12 hours for 7-10 days (i.e. 1 tablet per 4.5kg bodyweight twice daily). For the treatment of superficial pyoderma administer 11mg/kg every 24 hours (i.e 2 tablets per 4.5kg bodyweight once daily). Continue treatment for at least 21 days. For the treatment of osteomyelitis administer 11mg/kg every 12 hours (i.e. 2 tablets per 2.5kg bodyweight twice daily) for at least 28 days.

For further information see package leaflet.

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 25mg 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

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

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 veterinary surgeon.

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 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 08007/4104

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 25mg Tablets

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each tablet contains 25mg Clindamycin (as Clindamycin Hydrochloride)

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

100 Tablets

4. ROUTE(S) OF ADMINISTRATION

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

For further information, see package leaflet.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

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 25mg (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

Pharmacological Properties: ATCvet code: QJ01FF01

Clindamycin, a chlorinated analogue of lincomycin, is an antibiotic with bacteriostatic action. Bactericidal actions have also been reported. Clindamycin is rapidly absorbed; following oral administration up to 90% of the active ingredient is absorbed from the gastro-intestinal tract

Bioavailability is greater in fasting dogs than fed dogs. Clindamycin crosses the placental barrier and can be detected in milk.

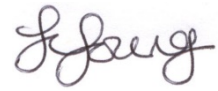
Shelf life: Clindacyl 25mg tablets Shelf life 3 years, Clindacyl 75 mg tablets Shelf life 3 years, Clindacyl 150 mg tablets Shelf life 3 years,

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

A handwritten signature in dark ink, appearing to read "J. Berg", is positioned below the approval date.

Product not marketed