

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mycinor 300 mg Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each tablet contains 300 mg Clindamycin (as 325.2 mg Clindamycin hydrochloride)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

A white to off-white caplet-shaped tablet with a score line on both sides. The tablet can be divided into two equal parts.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Mycinor 300 mg Tablets are indicated for use in dogs as follows:

For the treatment of infected wounds and abscesses, and infected mouth cavity and dental infections, caused by or associated with *Staphylococcus* spp, *Streptococcus* spp (except *Streptococcus faecalis*), *Bacteroides* spp, *Fusobacterium necrophorum*, and *Clostridium perfringens*. To help provide antimicrobial cover during dental procedures.

For the treatment of superficial pyoderma associated with *Staphylococcus intermedius*.

For the treatment of osteomyelitis, caused by *Staphylococcus aureus*.

Before Clindamycin therapy is initiated, the involved pathogens should be identified and sensitivity to clindamycin established.

4.3 Contraindications

Do not use in known cases of hypersensitivity to clindamycin, lincomycin or to any of the excipients.

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

4.4 Special Warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals

Clindamycin and erythromycin show parallel resistance. Partial cross-resistance has been demonstrated between clindamycin, erythromycin and other macrolides antibiotics.

During prolonged therapy of one month or greater, periodic liver and kidney function tests and blood counts should be performed.

Animals 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.

ii. Special Precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after handling tablets.

Care should be taken to avoid accidental ingestion.

In case of accidental ingestion, particularly by children, seek medical advice immediately and show the package leaflet or label to the doctor.

4.6 Adverse reactions (frequency and seriousness)

Vomiting and diarrhoea have occasionally been observed.

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.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

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

Clindamycin should not be used concomitantly with chloramphenicol or macrolides as they both target the ribosome 50S subunit and antagonist effects may develop.

4.9 Amounts to be administered and administration route

For oral administration only.

1. For the treatment of infected wounds and abscesses, and infected mouth cavity and dental infections in dogs, administer either:

- 5.5 mg/kg of bodyweight every 12 hours for 7-10 days, or
- 11 mg/kg of bodyweight every 24 hours for 7-10 days

If no clinical response is seen within 4 days, redetermine the diagnosis. To help provide antimicrobial cover during dental procedures, a 10 day course is recommended. This should be initiated five days before dental therapy and continued for five days thereafter. In dogs, treatment may be extended to a maximum of 28 days based on clinical judgement.

2. For the treatment of superficial pyoderma in dogs, administer either:

- 5.5 mg/kg of bodyweight every 12 hours, or
- 11 mg/kg of bodyweight every 24 hours

Therapy of canine superficial pyoderma is usually recommended for 21 days, with extension of therapy based on clinical judgement.

3. For the treatment of osteomyelitis in dogs, administer:

- 11 mg/kg of bodyweight every 12 hours for a minimum of 28 days

If no clinical response is seen within 14 days, the treatment should be stopped and the diagnosis redetermined.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In a tolerance study a dose rate of 3 times the recommended dose of 11 mg/kg bodyweight of Clindamycin administered twice daily over a period of 30 consecutive days did not demonstrate adverse effects.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-infectives for systemic use; Antibacterials for systemic use; Macrolides, Lincosamides and Streptogramins; Clindamycin.

ATC vet code: QJ01FF01

5.1 Pharmacodynamic properties

Mycinor Tablets contain Clindamycin hydrochloride, which is a chlorinated analogue of the natural antibiotic produced by *Streptomyces lincolnensis* var *lincolnensis*. They are indicated for the treatment of infected wounds, abscesses, infected mouth cavities, dental infections and superficial pyoderma. Clindamycin is primarily a bacteriostatic agent whose action is through the inhibition of bacterial protein synthesis at the ribosomal (50s sub-unit) level. Its efficacy is time dependent and concentration independent, although it may show some bactericidal action when high concentrations are used to treat sensitive strains.

Clindamycin has in vitro activity against the following micro-organisms:

- Aerobic Gram-positive cocci, including: *Staphylococcus intermedius* and *Staphylococcus aureus* (penicillinase and non-penicillinase producing strains), *Staphylococcus epidermidis*, *Streptococcus* spp (except *Streptococcus faecalis*).
- Anaerobic Gram-negative bacilli, including: *Bacteroides* spp, *Fusobacterium* spp.
- Clostridia: Most *Cl.perfringens* are susceptible; other species such as *Cl. sporogenes* and *Cl. tertium* frequently are resistant to clindamycin.

Most Gram-negative aerobic bacteria are resistant, including the enterobacteriaceae . Cross-resistance will occur between clindamycin and lincomycin. Clindamycin should not be used simultaneously with chloramphenicol or macrolides as this may lead to antagonism and potential cross-resistance. In cases where inducible resistance is detected, clinical failure during treatment with clindamycin may occur by selection of resistant mutants and the use of clindamycin would be best avoided in severe infection.

5.2 Pharmacokinetic properties

Absorption:

Clindamycin hydrochloride is rapidly absorbed from the canine gastrointestinal tract following oral administration. Effective clindamycin

antibacterial serum levels are reached within 30 minutes following administration of the therapeutic dose.

Serum values:

Therapeutic serum levels of clindamycin can be maintained by oral administration of 5.5 mg/kg bodyweight every 12 hours or 11 mg/kg bodyweight every 24 hours; peak serum concentrations are on average reached 75 minutes after oral administration. The biological plasma half-life of clindamycin in the dog is approximately 5 hours. No accumulation of bioactivity has been observed in dogs after several oral administrations.

Metabolism and Excretion:

Extensive research of the metabolism and excretion pattern of clindamycin shows that the parent molecule as well as bioactive and bio-inactive metabolites are excreted via the urine and faeces. Nearly all bioactivity in the serum following oral administration is due to the parent molecule (clindamycin).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose, microcrystalline (Avicel PH102)
Lactose, Monohydrate
Povidone
Silicon dioxide
Croscarmellose sodium (AcDiSol)
Magnesium stearate

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months.

6.4 Special precautions for storage

Do not store above 25°C.
Store in a dry place.

6.5 Nature and composition of immediate packaging

Packs of 100 tablets in polypropylene tubs with low density polyethylene lids and cotton wool wadding.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co Down
BT35 6JP

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4310

9. DATE OF FIRST AUTHORISATION

07 March 2012

10. DATE OF REVISION OF THE TEXT

May 2017

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.

Approved 24 May 2017