DRAFT CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mycinor 25 mg Tablets for Dogs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 25 mg Clindamycin (as 27.1 mg Clindamycin hydrochloride)

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

150 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Mycinor 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

- 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.

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

  5.5 mg/kg of bodyweight every 12 hours
  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.

- 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.

Dosage table:

Bodyweight	Superficial pyoderma	Dental infection	Wounds and abscesses Osteomyelitis
	5,5 mg/kg ev.12h	11 mg/kg ev.24h	11 mg/kg ev.12h
4.5 kg	1 x 25 mg twice daily	2 x 25 mg once daily	2 x 25 mg twice daily
13.5 kg	1 x 75 mg Twice daily	1 x 150 mg once daily	1 x 150 mg twice daily
27 kg	1 x 150 mg twice daily	1 x 300 mg once daily	1 x 300 mg twice daily

8. WITHDRAWAL PERIOD

-

9. SPECIAL WARNING(S), IF NECESSARY

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.

Please read the package leaflet before use

User Warnings:

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.

10. EXPIRY DATE

D.O.M.:
Exp.:

11. SPECIAL STORAGE CONDITIONS

Store below 25°C in a dry place.
Keep container in outer carton.

12. SPECIAL 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

FOR ANIMAL TREATMENT ONLY

POM-V

Prescription Only Medicine

To be supplied only on veterinary prescription

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4307

17. MANUFACTURER'S BATCH NUMBER

B.N.:

DRAFT LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mycinor 25 mg Tablets for Dogs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains: Clindamycin 25mg (as 27.1 mg Clindamycin hydrochloride)

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

150 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For the treatment of infected wounds and abscesses, and infected mouth cavity and dental infections.

For the treatment of superficial pyoderma and osteomyelitis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Please read the package leaflet before use.

8. WITHDRAWAL PERIOD

-

9. SPECIAL WARNING(S), IF NECESSARY

Please read the package leaflet before use.

10. EXPIRY DATE

D.O.M.:
Exp.:

11. SPECIAL STORAGE CONDITIONS

Store below 25°C in a dry place.
Keep container in outer carton.

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BT35 6JP

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4307

17. MANUFACTURER'S BATCH NUMBER

B.N.:

DRAFT INSERT TEXT

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

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYCINOR TABLETS

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

A white to off-white tablet for oral administration. Mycinor Tablets are available in four strengths with the following active composition:
25 mg, 75 mg, 150 mg, 300 mg Clindamycin (as Clindamycin Hydrochloride)

4. INDICATION(S)

Mycinor 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.

5. CONTRAINDICATIONS

Do not use in animals that are hypersensitive to preparations containing clindamycin or lincomycin.

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.

6. ADVERSE REACTIONS

Vomiting and Diarrhoea have occasionally been observed.

Clindamycin sometimes causes the overgrowth of non sensitive organisms such as resistant clostridia and yeasts.

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 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.

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

  5.5 mg/kg of bodyweight every 12 hours
  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.

- 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.

Dosage table:

Bodyweight	Superficial pyoderma	Dental infection	Wounds and abscesses Osteomyelitis
	5,5 mg/kg ev.12h	11 mg/kg ev.24h	11 mg/kg ev.12h
4.5 kg	1 x 25 mg twice daily	2 x 25 mg once daily	2 x 25 mg twice daily
13.5 kg	1 x 75 mg Twice daily	1 x 150 mg once daily	1 x 150 mg twice daily
27 kg	1 x 150 mg twice daily	1 x 300 mg once daily	1 x 300 mg twice daily

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Store below 25°C in a dry place.
Keep out of reach of children.
Keep container in outer carton.

12. SPECIAL WARNINGS

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 periodic liver and kidney function tests and blood counts should be performed.

Dose with caution and monitor carefully using serum examination during high dose use in animals with pre-existing severe renal and/or hepatic impairment.

User Warnings:

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.

Use during pregnancy and lactation.

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.

Interactions with other medicinal products

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

Clindamycin should not be used concomitantly with chloramphenicol or macrolides as they antagonise each other at their site of action at the 50S ribosomal subunit.

Overdose

In a tolerance study a dose rate of 3 times the recommended dose of 11 mg/kg bodyweight of Mycinor 150 mg tablets administered twice daily over a period of 30 consecutive days did not demonstrate adverse effects.

***In vitro* activity:**

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*), *Pneumococcus* spp.
- Anaerobic Gram-negative bacilli, including: *Bacteroides* spp, *Fusobacterium* spp.
- Anaerobic Gram-positive non-spore-forming bacilli, including: *Propionibacterium* spp, *Eubacterium* spp, *Actinomyces* spp.
- Anaerobic and microaerophilic Gram-positive cocci, including: *Peptococcus* spp, *Peptostreptococcus* spp, *microaerophilic streptococci*.
- Clostridia: Most *Cl. perfringens* are susceptible; other species such as *Cl. sporogenes* and *Cl. tertium* frequently are resistant to clindamycin.
- Mycoplasma species: Most mycoplasma species are susceptible to clindamycin.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

25 April 2012

15. OTHER INFORMATION

POM-V

Prescription Only Medicine

To be supplied only on veterinary prescription

Distributed by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

Marketing Authorisation No.:
25mg: Vm 02000/4307
75mg: Vm 02000/4308
150mg: Vm 02000/4309
300mg: Vm 02000/4310

For Animal Treatment Only

Approved: 24 May 2017