PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Antirobe Capsules 75 mg

clindamycin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each capsule contains 75 mg clindamycin (as Clindamycin Hydrochloride)

3. PHARMACEUTICAL FORM

Capsules

4. PACKAGE SIZE

80 capsules

5. TARGET SPECIES

Dogs *(included as a pictogram)*

6. INDICATION(S)

See package leaflet for full indications, contra-indications, warnings etc.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only.

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

Bodyweight	**Superficial pyoderma[1], dental infections, wounds and abscesses**		**Osteomyelitis[1]**
	5.5 mg/kg ev. 12h	**11 mg/kg ev. 24h**	**11 mg/kg ev. 12 hr**
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
27.0 kg	1 x 150 mg twice daily	1 x 300 mg once daily	1 x 300 mg twice daily

[1] for dogs only

8. WITHDRAWAL PERIOD

-

9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet for full indications, contra-indications, warnings etc.

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

Disposal advice: Dispose of used packaging in the household refuse. Unused capsules 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
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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4005

17. MANUFACTURER’S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON BLISTER FOIL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Antirobe 75 mg

clindamycin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis

3. EXPIRY DATE

Expires end:

4. BATCH NUMBER

Batch:

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PACKAGE LEAFLET FOR:

Antirobe Capsules 25 mg, 75 mg, 150 mg & 300 mg

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

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Fareva Amboise
Zone Industrielle
37530 Poce-sur-Cisse
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Antirobe Capsules

25 mg, 75 mg, 150 mg, 300 mg.

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

Each capsule contains 25, 75, 150 or 300 mg clindamycin (as clindamycin hydrochloride).

4. INDICATION(S)

Dogs: 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*.

Cats: For the treatment of infected wounds and abscesses, and infected mouth cavity and dental infections, caused by bacteria sensitive to clindamycin. To help provide antimicrobial cover during dental procedures.

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

5. CONTRAINDICATIONS

The use of Antirobe Capsules is contra-indicated in animals which 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 gastro-intestinal disturbance.

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

Clindamycin hydrochloride has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents.

Antirobe Capsules should 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 sub-unit.

Antirobe 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.

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.

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/queens or breeding male dogs/cats has not been established.

6. ADVERSE REACTIONS

Vomiting and diarrhoea have occasionally been observed.

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration only.

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

Dosage table:

Bodyweight	**Superficial pyoderma[1], dental infections, wounds and abscesses**		**Osteomyelitis[1]**
	5.5 mg/kg ev. 12h	**11 mg/kg ev. 24h**	**11 mg/kg ev. 12 hr**
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
27.0 kg	1 x 150 mg twice daily	1 x 300 mg once daily	1 x 300 mg twice daily

[1] for dogs only

9. ADVICE ON CORRECT ADMINISTRATION

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10. WITHDRAWAL PERIOD(S)

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11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C

12. SPECIAL WARNING(S)

Operator Warnings: Wash hands after handling the capsules.

For animal treatment only

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

Clindamycin hydrochloride is rapidly absorbed from the canine and feline gastro-intestinal tract following oral administration. Effective clindamycin antibacterial serum levels are reached within 30 minutes following administration of the recommended dose.

The maximum dosage which is well tolerated orally by dogs is 300 mg/kg bodyweight. This is 27 times the indicated dosage for treatment of superficial pyoderma, infected wounds, abscesses, mouth cavity and dental infections.

POM-V

To be supplied only on veterinary prescription.

25 mg: Vm 42058/4003

75 mg: Vm 42058/4005

150 mg: Vm 42058/4002

300 mg: Vm 42058/4004

Not all presentations may be marketed.

Approved 21 August 2020