PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{OUTER PACKAGE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Antirobe 25 mg capsules

2. STATEMENT OF ACTIVE SUBSTANCES

Each capsule contains:

Active substance:
Clindamycin (as Clindamycin hydrochloride) 25 mg

3. PACKAGE SIZE

80 capsules.

150 capsules.

4. TARGET SPECIES

Dogs and cats. *(included as pictograms)*

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral administration.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5154

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {BLISTER FOIL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Antirobe 25 mg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

25 mg clindamycin.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Antirobe capsules for dogs and cats

25 mg, 75 mg, 150 mg and 300 mg

2. Composition

Each capsule contains:

Active substance:
Clindamycin (as Clindamycin hydrochloride) 25, 75, 150 or 300 mg

Excipients:

	25 mg capsules	75 mg capsules	150 mg capsules	300 mg capsules
Black Iron oxide (E172)				
Erythrosin (E127)				0.077 mg
Indigo carmine (E132)		0.071 mg		0.016 mg
Quinoline yellow (E104)	0.144 mg	0.044 mg		
Sunset yellow (E110)	0.002 mg			
Titanium dioxide (E171)	0.826 mg	0.829 mg	1.52 mg	1.28 mg

25 mg capsules: Hard opaque gelatin capsules, with yellow cap and white body.
75 mg capsules: Hard opaque gelatin capsules, with green cap and white body.
150 mg capsules: Hard opaque gelatin capsules, with white cap and body.
300 mg capsules: Hard opaque gelatin capsules, with lavender cap and body.

3. Target species

Dogs and cats.

4. Indications for use

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 therapy with the veterinary medicinal product is initiated, the involved pathogens should be identified and sensitivity to clindamycin established.

5. Contraindications

The use of the veterinary medicinal product 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.

6. Special warnings

None.

Special precautions for safe use in the target species:
Clindamycin and erythromycin show parallel resistance. Partial cross-resistance has been demonstrated between clindamycin, erythromycin and other macrolide 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.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after handling the capsules.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

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. The veterinary medicinal product 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.

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

7. Adverse events

Dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Vomiting, Diarrhoea

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this package leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral administration.

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 every 12 hr	**11 mg/kg every 24 hr**	**11 mg/kg every 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

-

10. Withdrawal periods

-

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

25 mg: Vm 42058/5154
75 mg: Vm 42058/5156
150 mg: Vm 42058/5153
300 mg: Vm 42058/5155

Packs of 80 capsules in blister packs or
Packs of 80 or 150 capsules in tubs.

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
Tel: +44 (0) 345 300 8034

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

17. 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.

POM-V