SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Antirobe 300 mg capsules for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Active substance:
Clindamycin (as Clindamycin hydrochloride) 300 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Maize starch	
Talc	
Magnesium stearate	
Lactose monohydrate	
Gelatin	96 mg
Titanium dioxide (E171)	1.28 mg
Erythrosin (E127)	0.077 mg
Indigo carmine (E132)	0.016 mg
Black Iron oxide (E172)	

Hard opaque gelatin capsules, with lavender cap and body.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

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.

3.3 Contraindications

Do not use 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.

3.4 Special warnings

None.

3.5 Special precautions for use

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 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.

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 capsules.

Special precautions for the protection of the environment:
Not applicable.

3.6 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. Reports should be sent, preferably via a veterinarian, to

either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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. 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.

3.9 Administration routes and dosage

Oral administration.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01FF01

4.2 Pharmacodynamics

The veterinary medicinal product contains Clindamycin hydrochloride. Clindamycin is a semi-synthetic antibiotic produced by 7(S)-chloro substitution of the 7(R)-hydroxy group of the natural antibiotic produced by *Streptomyces lincolnensis var. lincolnensis*.

Mode of Action:
Clindamycin inhibits bacterial protein synthesis at the ribosomal (50s sub-unit) level.

***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.

4.3 Pharmacokinetics

Absorption:
Clindamycin hydrochloride is rapidly absorbed from the canine and feline 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 and cat is approximately 5 hours. No accumulation of bioactivity has been observed in dogs or cats 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).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities
None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Packs of 80 capsules in polyvinyl chloride/aluminium foil blister packs, or packs of 80 or 150 capsules in high density polyethylene tubs (with low density polyethylene lids).

Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER

Vm 60021/3002

8. DATE OF FIRST AUTHORISATION

02 May 2002

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

January 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved: 15 April 2026