Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Antirobe Capsules, 25mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains: clindamycin (as Clindamycin Hydrochloride) 25 mg as active ingredient.

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Capsule, hard.
Hard gelatin capsule, yellow cap and white body with the markings 'Clin 25' and 'Pfizer' containing a white powder with black iron oxide.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

Antirobe Capsules 25 mg are indicated for use in dogs and cats as follows:

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.

4.3 Contraindications

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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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. Patients 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

Vomiting and diarrhoea have occasionally been observed. 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.

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

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. 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.

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 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
- 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

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.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use.

ATC vet code: QJ01F F01.

ANTIROBE Capsules contain 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*.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

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).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch,
Talc,
Magnesium Stearate,
Lactose

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

White high density polyethylene tubs with desiccant pack, sealed with white low density polyethylene tamper evident push-fit lid containing 80 or 150 capsules. Polyvinyl chloride/aluminium foil blister packs containing 80 capsules. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7th January 2006

10 DATE OF REVISION OF THE TEXT

May 2014