Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindacyl 75 mg Tablets for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substance
Clindamycin 75 mg
(as Clindamycin Hydrochloride)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A round white tablet with a breakline on one side.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

Clindacyl 75 mg Tablets are antibiotics indicated for the treatment of infected wounds, abscesses, pyoderma and oral cavity/dental infections caused by or associated with clindamycin-sensitive staphylococci, streptococci, pneumococci, bacteroidaceae, *Fusobacterium necrophorum, Clostridium perfringens* and osteomyelitis caused by *Staphylococcus aureus*. Clindacyl 75 mg Tablets can also be used to help provide antimicrobial cover during dental procedures.

4.3 Contraindications

Do not administer to animals with hypersensitivity to clindamycin and lincomycin preparations.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use

During prolonged osteomyelitis 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.

Treatment with clindamycin should be based on susceptibility testing.

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

Wash hands after the administration of the product. Persons with known hypersensitivity to lincosamides (lincomycin, clindamycin) should not handle the product.

4.6 Adverse reactions (frequency and seriousness)

Clindamycin and lincomycin show parallel-resistance. There is a partial cross-resistance to erythromycin and other macrolide-antibiotics.
Clindamycin sometimes causes the overgrowth of non-sensitive organisms such as resistant clostridia and yeasts. In cases of superinfection, appropriate measures should be taken according to the clinical situation.
Vomiting and diarrhoea are observed occasionally.

4.7 Use during pregnancy, lactation or lay

While high dose studies in rats suggests 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.

4.8 Interaction with other medicinal products and other forms of interactions

Neuromuscular blocking effects have been observed with clindamycin possible leading to an increase of efficacy of other neuromuscular blocking agents. The concomitant use of such drugs must be handled with care.

Clindamycin should be used simultaneously with chloramphenicol or macrolids because their action site is also the 50-S-subunit and antagonistic effects can possibly occur.

When Clindamycin and aminoglycoside antibiotics (e.g. gentamicin) are used simultaneously adverse interactions (acute renal failure) can not be fully excluded.

4.9 Amounts to be administered and administration route

For oral administration.

Infected wounds, abscesses, infections of the oral cavity and teeth:

5.5 mg/kg clindamycin every 12 hours (i.e. 1 tablet per 13.5 kg bodyweight twice daily). Treatment for pyoderma should continue for at least 3 weeks. Treatment may be extended to a maximum of 28 days based on clinical judgement.
If no improvement is seen within 4 days, the sensitivity of the pathogens involved should be redetermined.

To help provide antimicrobial cover during dental procedures, a 10 day course of 5.5 mg/kg every 12 hours is recommended (i.e. 1 tablet per 13.5 kg twice a day) beginning 5 days before the intended procedure and continue for 5 days thereafter.

Osteomyelitis:

11 mg/kg clindamycin every 12 hours (i.e. 2 tablets per 13.5 kg bodyweight twice daily) for at least 4 weeks.

When after 4 days (infected wounds, abscesses, infections of the oral cavity and teeth) or 14 days (osteomyelitis) the treatment of acute infections is not successful at new test of sensitivity of the pathogens or a change of the therapeutic regimen should be initiated.

If necessary the treatment may be continued for a longer period of time. The tablets are administered orally to the dog (with meat or other food).

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The LD50 for dogs is unknown.

Symptoms of toxicosis are emesis, inappetency and diarrhoea. In such cases the administration must be stopped and the symptoms should be treated by suitable therapeutic regimens.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinfectives for systemic use, lincosamides; clindamycin
ATC vet code: QJ01FF01

Clindamycin is bacteriostatic in action and inhibits bacterial biosynthesis by a reversible binding to the 50-S subunit of the bacterial ribosomes. Bactericidal properties have also been found.

Clindamycin is absorbed systematically quickly and nearly completely. Following oral administration up to 90% of the active ingredient is absorbed from the gastro-intestinal tract.

Maximal plasma concentrations are reached quickly after administration on an empty stomach than after administration following feeding. After a single administration of one tablet, in dogs, on an empty stomach maximum plasma levels of 5 µg/ml are found compared to 3.4 µg/ml in dogs following feeding.

Clindamycin crosses the placenta barrier and is detected in the foetal blood circulation and in the milk.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose
Sodium Lauryl Sulphate
Colloidal Silicon Dioxide
Magnesium Stearate
Lactose Monohydrate
Povidone
Crospovidone

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Polyethylene bottle with tamper evident snap-cap closures containing 50 and 100 tablets.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/049/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 September 2000
Date of last renewal: 31 August 2010

10 DATE OF REVISION OF THE TEXT

August 2019