Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindacyl 150 mg Tablets for Dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substance:	**Quantity:**
Clindamycin (as Clindamycin Hydrochloride)	150 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

An oblong 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 150 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 150 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 not be used concomitantly with chloramphenicol or macrolids because they antagonise each other at the site of action.

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

Infected wounds, abscesses, pyoderma, oral cavity/dental infections:
5.5 mg/kg clindamycin every 12 hours for 7 - 10 days (i.e. 1 tablet per 27 kg bodyweight twice daily). 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.
Treatment for pyoderma in dogs should continue for at least 3 weeks.

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 27 kg twice a day) beginning 5 days before the intended procedure and continue for 5 days thereafter.

For the treatment of osteomyelitis in dogs administer 11 mg/kg clindamycin every 12 hours for at least 4 weeks (i.e. 2 tablets per 27 kg bodyweight twice daily). If no improvement is seen within 14 days the sensitivity of the pathogens involved should be redetermined.

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

Doses of 300 mg/kg have been tolerated in dogs with no adverse reactions. Occasional vomiting, inappetency and diarrhoea have been observed. In such cases, treatment should be stopped immediately and the animals treated symptomatically.

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, a chlorinated analogue of lincomycin, is an antibiotic with bacteriostatic action. Bactericidal actions have also been reported.
Clindamycin is rapidly absorbed; following oral administration up to 90% of the active ingredient is absorbed from the gastro-intestinal tract.

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)

VPA10983/049/003

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