1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soluclin 25 mg/ml oral solution for cats and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Clindamycin 25 mg
(equivalent to 27.15 mg clindamycin hydrochloride)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ethanol (96 per cent) (E1510)	100 mg
Sorbitol, liquid (non-crystallising)	
Glycerol	
Propylene glycol	
Sodium cyclamate	
Sucralose	
Anise flavour	
Hydrochloric acid dilute	
Sodium hydroxide	
Water, purified	

Oral solution.
A colourless to slightly yellowish coloured solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats and dogs.

3.2 Indications for use for each target species

Cats:
For the treatment of infected wounds and abscesses caused by clindamycin-susceptible species of *Staphylococcus* spp. and *Streptococcus* spp..

Dogs:
- For the treatment of infected wounds, abscesses and oral cavity/dental infections caused by or associated with clindamycin-susceptible species of *Staphylococcus* spp., *Streptococcus* spp., *Bacteroides* spp., *Fusobacterium necrophorum*, *Clostridium perfringens*.
- Adjunctive treatment of mechanical or surgical periodontal therapy in the treatment of infections of the gingival and periodontal tissues.
- For the treatment of osteomyelitis caused by *Staphylococcus aureus*.

3.3 Contraindications

Do not use in hamsters, guinea pigs, rabbits, chinchillas, horses or ruminants because clindamycin ingestion by these species may cause severe gastrointestinal disorders.
Do not use in cases of hypersensitivity to either clindamycin or lincomycin, or to any of the excipients.

3.4 Special warnings

Cross-resistance has been shown between clindamycin and different antimicrobials belonging to lincosamides and macrolides classes (including erythromycin).
Use of clindamycin should be carefully considered when susceptibility testing has shown resistance to lincosamides and macrolides because its effectiveness may be reduced.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Use of the product should be based on identification and susceptibility testing of the target pathogen(s) including the D-zone test.
If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
Clindamycin is likely to favour the proliferation of non-susceptible organisms such as resistant *Clostridia* spp. and yeasts. In case of secondary infection, appropriate corrective measures should be taken based on clinical observations.
In case of administration of high doses of clindamycin or during prolonged therapy of one month or greater, tests for liver and renal functions and blood counts should be performed periodically.
In dogs and cats with kidney problems and/or liver problems, accompanied by severe metabolic aberrations, the dose to be administered should be carefully determined and their condition should be monitored by performing appropriate blood tests during treatment.
The use of the product is not recommended in neonates.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands carefully after use.
This veterinary medicinal product may cause hypersensitivity (allergic reaction). People with known hypersensitivity to lincosamides (clindamycin and lincomycin) should avoid contact with the veterinary medicinal product.
Care should be taken to avoid accidental ingestion as this may result in gastro-intestinal effects such as abdominal pain and diarrhoea.
In case of accidental ingestion, particularly by a child, or allergic reaction seek medical advice immediately and show the package leaflet or the label to the physician.
In order to limit the spread of resistant bacteria, general hygiene precautions should be implemented.
Washing hands with soap and water are especially recommended when handling the treated animals, their waste and their bedding material.

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

3.6 Adverse events

Cats and dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Vomiting and/or 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 its local representative or the national competent authority via the national reporting system. See the section 'Contact details' of the package leaflet.

3.7 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, the safety of the veterinary medicinal product in pregnant bitches/queens or breeding male dogs/cats has not been established. Use only according to the benefit/risk assessment by the responsible veterinarian.
Clindamycin can pass the placenta and blood-milk barrier. As a consequence, treatment of lactating females can cause diarrhoea in puppies and kittens.

3.8 Interaction with other medicinal products and other forms of interaction

-Aluminium salts and hydroxides, kaolin and Aluminium-Magnesium-Silicate complex may reduce the gastrointestinal absorption of lincosamides. Products containing these substances should be administered at least 2 hours before clindamycin.
-Cyclosporin: clindamycin may reduce levels of this immunosuppressive drug with a risk of lack of activity.
-Neuro-muscular blocking agents: clindamycin possesses intrinsic neuromuscular blocking activity and should be used cautiously with other neuromuscular blocking agents (curares). Clindamycin may increase neuromuscular blockade.
-Do not use clindamycin simultaneously with chloramphenicol or macrolides as they both target the ribosome 50S subunit and antagonist effects may develop.
-When using clindamycin and aminoglycosides (e.g. gentamicin) simultaneously, the risk of adverse interactions (acute renal failure) cannot be excluded.

3.9 Administration routes and dosage

For oral use.

Recommended dose:

Cats:
Infected wounds, abscesses: 11 mg of clindamycin per kg of body weight (i.e. approximately 0.5 mL of product / kg bw) per 24 hours or 5.5 mg / kg (i.e. approximately 0.25 mL of product / kg bw) per 12 hours for 7 to 10 days.
The treatment should be stopped if no therapeutic effect is observed after 4 days.

Dogs:
- Infected wounds, abscesses and oral cavity/dental infections: 11 mg clindamycin per kg of bodyweight (i.e. approximately 0.5 mL of product / kg bw) per 24 hours or 5.5 mg / kg (i.e. approximately 0.25 mL of product / kg bw) per 12 hours for 7 to 10 days.
  The treatment should be stopped if no therapeutic effect is observed after 4 days.
- Treatment of bone infections (osteomyelitis): 11 mg clindamycin per kg of body weight (i.e. approximately 0.5 mL of product / kg bw) per 12 hours for a period of 28 days minimum. The treatment should be discontinued if no therapeutic effect is observed in the first 14 days.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

A 3 ml graduated syringe is provided to facilitate the administration of the veterinary medicinal product.

The solution can be administered directly into the mouth of the animal or added to a small quantity of food.

Instructions: remove the cap from the bottle, insert the syringe tip into the adapter of the bottle, invert the bottle to draw up the required dose, return the bottle to an upright position and remove the syringe from the bottle.

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

No adverse effects have been reported in dogs after administration of high dosage up to 300 mg/kg clindamycin. Vomiting, loss of appetite, diarrhoea, leukocytosis and elevated liver enzymes (AST/SGOT and ALT/SGPT) have been observed occasionally. In such cases, discontinue the treatment and administer a symptomatic treatment.

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

Clindamycin is mainly a bacteriostatic antibiotic belonging to the group of lincosamides. Clindamycin is a chlorinated analogue of lincomycin. It works by inhibiting bacterial protein synthesis. The reversible coupling to the sub-unit 50-S bacterial ribosome inhibits translation of amino acids linked to the tRNA, thereby preventing elongation of the peptide chain.
Clindamycin and lincomycin have cross-resistance, which is also common between erythromycin and other macrolides.
Acquired resistance can occur, by methylation of the ribosomal binding site via chromosomal mutation in gram positive bacteria, or by plasmid-mediated mechanisms in gram negative bacteria.
CLSI clindamycin veterinary breakpoints are available in *Staphylococcus* spp. and *Streptococci*-ß-haemolytic group isolates from dogs with skin and soft tissue infections: S ≤0.5µg/ml; I=1-2µg/ml; R≥4µg/ml (CLSI 2020).
The incidence of resistance to lincosamides in *Staphylococcus* spp. appears to be wide-ranging in Europe with a weighted arithmetic mean of resistance about 25% in *Staphylococcus pseudintermedius* and in *Staphylococcus aureus* (EFSA, 2021).

4.3 Pharmacokinetics

Clindamycin is almost completely absorbed after oral administration.
Dogs:
After dosing of 11 mg of clindamycin /kg bw, maximum plasma concentrations are reached within 0.25 to 1.5 hours (Tmax) with a mean half-life of 5.21 hours. C_{max} of 4272 ng/ml and $AUC_{0\text{-last}}$ of 23473 ng.h/ml are observed.
Cats:

After dosing of 11 mg of clindamycin /kg bw, maximum plasma concentrations are reached within 0.25 to 1.5 hours (Tmax) with a mean half-life of 4.20 hours. C_{max} of 3816 ng/ml and $AUC_{0\text{-last}}$ of 21405 ng.h/ml are observed
Clindamycin is widely distributed and may concentrate in some tissues.
Approximately 70% is excreted in faeces and 30% in the urine.

Clindamycin is approximately 93% bound to plasma proteins.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years
Shelf life after first opening the immediate packaging: 3 months

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Amber type III glass bottle closed with white polypropylene child-resistant closure and Low-Density Polyethylene (LDPE) syringe adaptor.
A 3 mL LDPE/polystyrene graduated syringe is supplied with each bottle.

Each bottle is packed in a cardboard box.

Package sizes:
Cardboard box with 1 glass bottle of 10 mL
Cardboard box with 1 glass bottle of 25 mL
Cardboard box with 1 glass bottle of 50 mL

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
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

CP-Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10810/027/001

8. DATE OF FIRST AUTHORISATION

14/08/2023

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

10/10/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database *(https://medicines.health.europa.eu/veterinary)*.