ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soluclin 25 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Clindamycin 25 mg
(equivalent to 27.15 mg clindamycin hydrochloride)

3. PACKAGE SIZE

10 ml
25 ml
50 ml

4. TARGET SPECIES

Cats and dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

CP Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

Vm 20916/3009

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{amber glass bottle type III or high density polyethylene bottle, 50ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soluclin 25 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Clindamycin 25 mg
(equivalent to 27.15 mg clindamycin hydrochloride)

3. TARGET SPECIES

Cats and dogs.

4. ROUTES OF ADMINISTRATION

For oral use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

CP Pharma Handelsgesellschaft mbH

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{amber glass bottle type III or high density polyethylene bottle 10ml/ 25ml/30ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soluclin 25 mg/ml

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
Clindamycin 25 mg
(equivalent to 27.15 mg clindamycin hydrochloride)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Soluclin 25 mg/ml oral solution for cats and dogs

2. Composition

Each ml contains:

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

Excipient:
Ethanol (96 per cent) (E1510) 100 mg

Oral solution.
A colourless to slightly yellowish coloured solution.

3. Target species

Cats and dogs.

4. Indications for use

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*.

5. 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.

6. Special warnings

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.

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.

Other precautions:
Not applicable.

Pregnancy and lactation:
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.
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.

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.

Overdose:
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.

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

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 months.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Amber type III glass bottle or white high-density polyethylene 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
Cardboard box with 1 HDPE bottle of 10 mL
Cardboard box with 1 HDPE bottle of 25 mL
Cardboard box with 1 HDPE bottle of 50 mL

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany
Only in case marketing authorisation holder is also the local contact to report suspected adverse reactions: Tel: +49 (0)5136 60660

Local representatives and contact details to report suspected adverse reactions:

United Kingdom (Northern Ireland)
CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany
Tel.: +49 5136 60660
info@cp-pharma.de

17. Other information

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