<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindaseptin 25 mg/ml Oral Solution for Cats & Dogs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each mL contains 25mg clindamycin and ethanol 9.05%.

3. PHARMACEUTICAL FORM

Oral Solution

4. PACKAGE SIZE

22 ml

5. TARGET SPECIES

Cats and Dogs.

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
Ireland

Distributor:
Vetoquinol UK Limited
Pury Hill Business Park
Towcester, Northants
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08749/4032

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindaseptin 25 mg/ml Oral Solution for Cats & Dogs.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Clindamycin 25mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

22 ml

4. ROUTE OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET
Clindamycin 25 mg /ml Oral Solution for Cats & Dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
Ireland

Distributor:
Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northants
NN12 7LS

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindaseptin 25 mg/ml Oral Solution for Cats & Dogs.
Clindamycin

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENT

One ml contains:
Active substance:
Clindamycin 25 mg
(as Clindamycin hydrochloride 27.15 mg)
Excipients
Ethanol 96 % 90.56 mg

Clear, colourless solution.

4. INDICATIONS

Cats:
For the treatment of infected wounds and abscesses caused by clindamycin-sensitive 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-sensitive species of *Staphylococcus*

spp., *Streptococcus* spp., *Bacteroides* spp., *Clostridium perfringens, Fusobacterium necrophorum.*

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

6. ADVERSE REACTIONS

In very rare cases, lethargy (tiredness), vomiting and diarrhoea may be observed. Clindamycin sometimes causes the overgrowth of non-sensitive organisms such as resistant *clostridia* and yeasts. In case of secondary infection, the treatment should be stopped and appropriate measures should be taken based on clinical observations.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)

very rare (less than 1 animal in 10,000 animals, including isolated reports).

7. TARGET SPECIES

Cats & Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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

Recommended dosage:
Cats:
- infected wounds, abscesses: 11 mg clindamycin per kg of body weight per 24h or 5.5 mg /kg per 12h 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 body weight per 24h or 5.5 mg /kg per 12h 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 every 12 hours during a period of 28 days minimum. The treatment should be discontinued if no therapeutic effect is observed in the first 14 days.

Dosage	Volume to be administered per kg bodyweight
5.5 mg/kg	Corresponding approximately to 0.25 ml per kg
11 mg/kg	Corresponding approximately to 0.5 ml per kg

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Not Applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use after the expiry date stated on the label and carton after EXP.
Shelf-life after first opening the container: 28 days

12. SPECIAL WARNINGS

Special precautions for use in animals
Inappropriate use of the product may increase the prevalence of bacteria resistant to clindamycin.
Whenever possible, clindamycin should only be used based on susceptibility testing. See Section 15 for information on clinical breakpoints for clindamycin.
Official national and local antimicrobial policies should be taken into account when the product is used.
Clindamycin shows parallel-resistance with lincomycin and co-resistance with erythromycin. There is a partial cross-resistance to erythromycin and other macrolides.
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 serum tests during treatment.
The use of the product is not recommended in neonates (infants).

Special precautions to be taken by the person administering the medicinal product to animals
Wash hands after administration.
People with known hypersensitivity to lincosamides (lincomycin and clindamycin) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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

Interaction with other medicinal products and other forms of interaction
- Aluminium salts and hydroxides, kaolin and Aluminium-Magnesium-Silicat complex may reduce Clindamycins digestive absorption. These digestive topics 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 which are used as muscle relaxants during surgery). Clindamycin may increase neuromuscular blockade causing paralysis in the skeletal muscle of the animal.

- Do not use clindamycin simultaneously with chloramphenicol or macrolides (erythromycin) as they may impair each other's effect.

- When using simultaneously clindamycin and aminoglycosides (i.e gentamicin), the risk of adverse interactions (acute renal failure) cannot be excluded.

Overdose (symptoms, emergency procedures, antidotes), if necessary
Doses of 300 mg / kg were tolerated by dogs without having adverse effects. Vomiting, loss of appetite, diarrhoea, leukocytosis and elevations in liver enzymes (AST, ALT) were observed occasionally. In such cases, discontinue treatment immediately and establish a symptomatic treatment.

Incompatibilities
Do not mix this product with any other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

MM/YYYY

15. OTHER INFORMATION

Pack size:
Carton box of one bottle of 22 mL

CLSI clindamycin veterinary breakpoints are available for dogs in *Staphylococcus* spp. and Streptococci-ß-haemolytic group in skin and soft tissue infections: S ≤ 0.5 µg/ml; I=1-2µg/ml; R ≥ 4 µg/ml. (CLSI July 2013).

Approved: 19 April 2018