PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OTIMECTIN vet. 1 mg/g ear gel for cats
Ivermectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each g gel contains
Ivermectin 1 mg

3. PHARMACEUTICAL FORM

Ear gel.

4. PACKAGE SIZE

10 g.

5. TARGET SPECIES

Cats.

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

For auricular use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP (month/year)
Shelf life after first opening the immediate packaging: 28 days

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Do not refrigerate or freeze.

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

Disposal: read package leaflet.

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

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Le Vet B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

ALUMINIUM TUBE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OTIMECTIN vet. 1 mg/g ear gel for cats
Ivermectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ivermectin 1 mg/g

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

10 g.

4. ROUTE(S) OF ADMINISTRATION

For auricular use.

5. WITHDRAWAL PERIOD

-

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP (month/year)
Once opened, use by_____

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

OTIMECTIN vet. 1 mg/g ear gel for cats

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

Marketing authorisation holder:
Le Vet B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer for the batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

OTIMECTIN vet. 1 mg/g ear gel for cats
(Ivermectin)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Description
Colourless to slightly yellow, slightly opalescent and viscous gel.

Active substance per g:
Ivermectin 1 mg

4. INDICATION(S)

Treatment of ear mite (*Otodectes cynotis*) infestation in cats.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use if the tympanic membrane is perforated.
Do not use if the tympanic membrane cannot be fully visualized.
Do not use in cats with obstructed external ear canals due to chronic inflammation.
Do not use in cats suffering from systemic disorders.

6. ADVERSE REACTIONS

Accidental use in kittens and cats with perforated ear drums or obstructed external ear canal may lead to side effects characterized by depression of the central nervous system associated with apathy, anorexia, mydriasis, ataxia, tremors and salivation.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

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

Posology
For local administration in the external ear canal.
Fill the external ear canal with the product. This provides a dose of approximately 1 gram of the veterinary medicinal product (equivalent to 1 mg ivermectin) per ear. Massage gently for even distribution by pressing from the outside on the auricle.
Repeat administration after 7 days and 14 days.
A further veterinary examination after treatment is recommended as it may be necessary to repeat or reconsider the treatment
Directions for use
Rinse or clean the ears before using OTIMECTIN.
Both ears should be treated.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25°C.
Do not refrigerate or freeze.
Do not use after expiry date stated on the tube and the carton.
Once opened, use by 28 days.

12. SPECIAL WARNING(S)

Special warnings for the target species
All the cats housed together should be treated simultaneously against O*todectes cynotis* infestation.
Other receptive companion animals (dogs, ferrets) in the household should be treated as well with another suitable product when the presence of ear mite is detected and confirmed.

Special precautions for use in animals
In the absence of available information on safety the product should not be used on cats under 16 weeks of age.
Care should be taken to avoid that the product comes into contact with the eyes or mouth after administration.
Care should be taken to ensure that cats do not ingest the product by mutual or self grooming at the site of application.
Avermectins may not be well tolerated in all non target species. Cases of intolerance are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles and tortoises.
Dogs and cats should not be allowed to ingest spilled gel or have access to used packaging due to the potential for adverse effects related to ivermectin toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product may cause sensitisation by contact, therefore avoid direct contact with skin and eyes during and after application.
Wash hands and any exposed area after use.
Precautions should be taken to avoid splashes to the face and/or eyes should the animal shake its head following instillation of the product.

Use during pregnancy and lactation
Studies in laboratory animals have not produced any evidence of teratogenic or foetotoxic effects at concentrations used in this product. The safety of the product was not assessed in pregnant or lactating queens. The product should be used accordingly to thee benefit/risk assessment by the responsible veterinarian in pregnant and lactating animals.

Overdose (symptoms, emergency procedures, antidotes)(if necessary)
No signs of overdose have been observed following aural administration of two treatments seven days apart at five times the recommended dose of ivermectin.

Interaction with other medicinal products and other forms of interaction
Concomitant treatment with any drug interacting with P-glycoproteins should be avoided (e.g. selamectin and piperazine). The effects of medication that binds to the GABA-receptor may be increased by ivermectin.

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

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

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

Will follow.

15. OTHER INFORMATION

Pharmacodynamic properties
Ivermectin belongs to the group of avermectins, a family of closely related macrocyclic lactones. Ivermectin has a broad antiparasitic activity against nematodes and arthropods. It acts by inhibiting nerve impulses. Compounds of the macrocyclic lactone class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the relevant parasites. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).
Resistance has not been observed in *Otodectes cynotis*.
The effectiveness of the product might be partly related to a physical effect of the excipients.

Pharmacokinetic particulars
Pharmacokinetic data on ivermectin after local administration in the ear of cats indicate absorption and slow elimination of ivermectin, resulting in mean residual plasma concentrations of about 20 ng/ml 6.5 days after the third treatment.

Package (size)
Tube consisting of aluminium with an external coating of white polyurethane and an internal coating of epoxy resin and a screw cap of polyethylene containing 10 gram gel.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.