SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otimectin vet. 1 mg/g ear gel for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains
Active substance:
Ivermectin 1 mg

Excipients:
For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 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.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy and lactation

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

4.8 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 GABA-ergics may be increased by ivermectin.

4.9 Amounts to be administered and administration route

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 the product.
Both ears should be treated.

4.10 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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutical group: otologicals, antiparasitics.
ATCvet code: QS02QA03.

5.1 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.

5.2 Pharmacokinetic particulars

Pharmacokinetic data on iveremectin 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxyethylcellulose
Propylene glycol (E490).

6.2 Incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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.

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

Do not contaminate surface waters or ditches with product or used container since ivermectin is extremely dangerous to fish and aquatic life.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

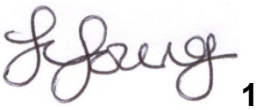
Vm 19994/4032

9. DATE OF FIRST AUTHORISATION

16 November 2012

10. DATE OF REVISION OF THE TEXT

December 2013

Approved:  **12/12/2013**