1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oridermyl ear gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances:
Permethrin technical cis/trans ratio 25:75 ……..……. 10 mg
Neomycin (as neomycin sulfate) ……..…… ……. 3500 IU
Nystatin ……..……..……..……..……..……. 100 000 IU
Triamcinolone acetonide ……..…..……..……..……. 1 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Polyethylene wax	
Liquid paraffin.	

Pale yellow gel.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the treatment of mixed ear infections (otitis externa) due to bacteria sensitive to neomycin, yeasts sensitive to nystatin and ear mites (*otodectes cynotis*) sensitive to permethrin.

3.3 Contraindications

Do not use in animals with perforated tympanic membrane, as this may lead to ototoxicity and deafness.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

See section 3.5.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Accidental ingestion may lead to absorption of the active substances triamcinolone and permethrin. Do not allow any surplus ointment to remain on the coat in order to avoid accidental ingestion by licking or grooming.
Prior to use, the integrity of the ear drum should be confirmed. During administration, press the tube while slowly withdrawing the cannula in order to avoid tympanic pressure.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash your hands with water and soap after administering the product.
In case of contact with eyes or skin, rinse immediately with plenty of water.
In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.
People with known hypersensitivity to any of the ingredients should avoid contact with the veterinary medicinal product.

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

Other precautions:
Cats are particularly sensitive to the effects of permethrin if ingested. Accidental ingestion may lead to adverse effects including salivation, agitation and vomiting in cats.

3.6 Adverse events

Dogs, cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Skin disorder[1] Application site irritation[2]

[1] Prolonged local use may lead to skin sensitisation and possible cross sensitivity to other aminoglycosides.
[2] Minor. If irritation persists or worsens, administration should be stopped.

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 package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Pregnancy and lactation:

Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Auricular use.
After cleaning the external ear, introduce a pea-sized quantity (approximately 0.3 ml) of the veterinary medicinal product and massage the base of the ear gently. Clean any surplus product from the ear flap. Treat once a day until healing occurs. The recommended duration of treatment is 21 days (duration of reproduction cycle of *Otodectes cynotis*).

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

In dogs with healthy ears, doses equivalent to 4 times the therapeutic dose for twice the recommended treatment duration led to minor irritation.

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:

QS02CA04

4.2 Pharmacodynamics

Triamcinolone acetonide is a synthetic glucocorticosteroid used in the veterinary medicinal product for its anti-inflammatory and anti-pruritic properties.
Neomycin sulphate is an antibiotic of the aminoglycoside group with a bactericidal action on many Gram negative aerobic bacteria and on some *Staphylococcus* strains.
Nystatin is an antifungal with a spectrum of activity oriented against yeasts of *Candida* and *Malassezia* type and fungi.
Permethrin is a type I synthetic pyrethroid, that is acaricide and insecticide. It acts on sodium channels and blocks the nerve impulse transmission in insects.

4.3 Pharmacokinetics

Data in literature show that resorption of nystatin, neomycin and permethrin through healthy skin is very limited. Systemic absorption of triamcinolone acetonide cannot be excluded.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

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

Aluminium tube of 10g with high-density polyethylene cap.

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

Vetoquinol Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10983/040/001

8. DATE OF FIRST AUTHORISATION

13/06/2008

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

14/11/2024

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).