

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Oridermyl ear gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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 to	1	g

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ear gel.
Pale yellow gel.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

In dogs:
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.

4.3 Contraindications

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

4.4 Special warnings for each target species

See section 4.5.

4.5 Special precautions for use

Special precautions for use in animals

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.

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.

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 to the physician.

People with known hypersensitivity to any of the ingredients should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Prolonged local use may lead to skin sensitisation and possible cross sensitivity to other aminoglycosides.

Minor irritation may occur following administration. If irritation persists or worsens, administration should be stopped.

4.7 Use during pregnancy, lactation or lay

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

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

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

By auricular route.

After cleaning the external ear, introduce a pea-sized quantity (approximately 0.3 ml) of Oridermyl 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*).

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal Period(s)

Not applicable

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: otologicals; corticosteroids and antiinfectives in combination; triamcinolone and antiinfectives.

ATC vet code: QS02CA04

5.1 Pharmacodynamic properties

Triamcinolone acetonide is a synthetic glucocorticosteroid used in Oridermyl 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.

5.2 Pharmacokinetic properties

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene wax

Liquid paraffin.

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Aluminium tube of 10g with high-density polyethylene cap

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
First Floor, Segrave House
19/20 Earlsfort Terrace
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10983/040/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th June 2008

Date of last renewal: 24th May 2013

10 DATE OF REVISION OF THE TEXT

August 2015