

# Otisor

Authorised

- Miconazole nitrate
- Prednisolone acetate
- POLYMYXIN B SULFATE

## Product identification

**Medicine name:**

Otisor

**Active substance:**

Miconazole nitrate

Prednisolone acetate

POLYMYXIN B SULFATE

**Target species:**

Dog

Cat

**Route of administration:**

Auricular use

Cutaneous use

## Product details

**Active substance and strength:**

Miconazole nitrate

23.00 milligram(s) / 1.00 millilitre(s)

Prednisolone acetate

5.00 milligram(s) / 1.00 millilitre(s)

POLYMYXIN B SULFATE

5500.00 international unit(s) / 1.00 millilitre(s)

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**Pharmaceutical form:**

Ear drops, suspension

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QS02CA01

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Croatia

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**Package description:**

30 ml white low-density polyethylene squeeze dropper bottle with a white, high-density polyethylene cap (screw fit), and a white, low-density polyethylene dropper.  
15 ml white low-density polyethylene squeeze dropper bottle with a white, high-density polyethylene cap (screw fit), and a white, low-density polyethylene dropper.

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Hybrid application (Article 13(3) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Chanelle Pharmaceuticals Manufacturing Limited

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**Marketing authorisation date:**

27/11/2023

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**Manufacturing sites for batch release:**

Chanelle Pharmaceuticals Manufacturing Limited

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**Responsible authority:**

Ministry Of Agriculture Veterinary And Food Safety Directorate

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**Authorisation number:**

UP/I-322-05/23-01/787

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**Date of authorisation status change:**

27/11/2023

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**Reference member state:**

Ireland

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**Procedure number:**

IE/V/0659/001

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**Concerned member states:**

Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland  
France Germany Greece Hungary Italy Latvia Lithuania Netherlands  
Norway Poland Portugal Romania Slovenia Spain Sweden

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[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

Summary of Product Characteristics

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