

# Otisur

Authorised

- Miconazole nitrate
- Prednisolone acetate
- POLYMYXIN B SULFATE

## Product identification

### **Medicine name:**

Otisur

Otisur 23,0 mg/ml + 5,0 mg/ml + 5500 UI/ml gocce auricolari, sospensione per gatti e cani

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### **Active substance:**

Miconazole nitrate

Prednisolone acetate

POLYMYXIN B SULFATE

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### **Target species:**

Dog

Cat

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### **Route of administration:**

Auricular use

Cutaneous use

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## 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:**

Italy

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**Package description:**

Available only in Italian

Available only in Italian

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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:**

15/06/2023

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**Manufacturing sites for batch release:**

Chanelle Pharmaceuticals Manufacturing Limited

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**Responsible authority:**

Ministry Of Health

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**Authorisation number:**

105615

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**Date of authorisation status change:**

15/06/2023

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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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## Documents

### Combined File of all Documents

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### Summary of Product Characteristics