

# Mitex Ohrentropfen und Suspension zur Anwendung auf der Haut für Hunde und Katzen

Authorised

- Miconazole nitrate
- Prednisolone acetate
- POLYMYXIN B SULFATE

## Product identification

### **Medicine name:**

Mitex Ohrentropfen und Suspension zur Anwendung auf der Haut für Hunde und Katzen

### **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:**

Cutaneous/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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**Available in:**

Croatia

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**Package description:**

Available only in [Croatian](#)

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Generic application (Article 13(1) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Vetviva Richter GmbH

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**Marketing authorisation date:**

6/05/2015

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**Manufacturing sites for batch release:**

Vetviva Richter GmbH

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**Responsible authority:**

Ministry Of Agriculture Veterinary And Food Safety Directorate

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**Authorisation number:**

UP/I-322-05/19-01/684

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**Date of authorisation status change:**

30/01/2025

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**Reference member state:**

Austria

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**Procedure number:**

AT/V/0014/001

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**Concerned member states:**

Belgium Bulgaria Croatia Czechia Denmark Estonia Finland France  
Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania  
Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain  
Sweden United Kingdom (Northern Ireland)

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To consult adverse reactions on veterinary medicinal products please go to  
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## Documents

Summary of Product Characteristics

English (PDF)

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