

# 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:**

Germany

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**Available in:**

Germany

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**Package description:**

Dropper container of white, opaque LDPE with white, opaque HDPE screw cap in a cardboard box. Pack size: 1 x 20 ml

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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:**

3/03/2015

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**Manufacturing sites for batch release:**

Vetviva Richter GmbH

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**Responsible authority:**

Federal Office Of Consumer Protection And Food Safety

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**Authorisation number:**

402105.00.00

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**Date of authorisation status change:**

24/10/2019

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

## Documents

Combined File of all Documents

This document does not exist in this language (English). You can find it in another language below.

Summary of Product Characteristics

at-puar-atv0014001-mr-mitex-en.pdf