

# Otomicol ear drops and cutaneous suspension for dogs, cats and guinea pigs

Authorised

- Miconazole nitrate
- Prednisolone acetate
- POLYMYXIN B SULFATE

## Product identification

### **Medicine name:**

Otomicol ear drops and cutaneous suspension for dogs, cats and guinea pigs

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### **Active substance:**

Miconazole nitrate

Prednisolone acetate

POLYMYXIN B SULFATE

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### **Target species:**

Cat

Dog

Guinea pig

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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:**

Germany

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**Package description:**

(ID1) 15 millilitre(s): Box (Cardboard) with 1 Bottle (Low Density PolyEthylene) with 15 millilitre(s), closed with Tropfer and Verschluss mit Originalitätssicherung (Low Density PolyEthylene, High Density PolyEthylene)

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Hybrid application – bioavailability studies cannot be used to demonstrate bioequivalence (Article 19(1)(b) of Regulation (EU) 2019/6)

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**Marketing authorisation holder:**

KRKA tovarna zdravil d.d. Novo mesto

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**Marketing authorisation date:**

20/06/2024

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**Manufacturing sites for batch release:**

KRKA tovarna zdravil d.d. Novo mesto

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**Responsible authority:**

Federal Office Of Consumer Protection And Food Safety

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**Authorisation number:**

V7014442.00.00

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**Date of authorisation status change:**

20/06/2024

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**Reference member state:**

Germany

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**Procedure number:**

DE/V/0342/001

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**Concerned member states:**

Belgium Bulgaria Croatia Czechia Estonia France Greece Hungary Ireland  
Italy Latvia Lithuania Netherlands Poland Portugal Romania Slovakia  
Slovenia Spain 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

English (PDF)

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