# 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

**Active substance:**
Miconazole nitrate
Prednisolone acetate
POLYMYXIN B SULFATE

**Target species:**
Cat
Dog
Guinea pig

**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)

**Pharmaceutical form:**
Ear drops, suspension

**Anatomical therapeutic chemical veterinary (ATCvet) codes:**
QS02CA01

**Legal status of supply:**
Veterinary medicinal product subject to veterinary prescription

**Authorisation status:**
Valid

**Authorised in:**
France

**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)

## Additional information

**Entitlement type:**
Marketing Authorisation

**Legal basis of product authorisation:**

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

**Marketing authorisation holder:**
KRKA tovarna zdravil d.d. Novo mesto

**Marketing authorisation date:**
5/07/2024

**Manufacturing sites for batch release:**
KRKA tovarna zdravil d.d. Novo mesto

**Responsible authority:**
French Agency For Food, Environmental And Occupational Health & Safety

**Authorisation number:**
FR/V/3345349 5/2024

**Date of authorisation status change:**
5/07/2024

**Reference member state:**
Germany

**Procedure number:**
DE/V/0342/001

**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)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

## Documents

Package Leaflet and Labelling

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