

# Otisur

Authorised

- Miconazole nitrate
- Prednisolone acetate
- POLYMYXIN B SULFATE

## Product identification

**Medicine name:**

Otisur

**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)

---

**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:**

Croatia

---

**Package description:**

30 ml white low-density polyethylene squeeze dropper bottle with a white, high-density polyethylene cap (screw fit), and a white, low-density polyethylene dropper.  
15 ml white low-density polyethylene squeeze dropper bottle with a white, high-density polyethylene cap (screw fit), and a white, low-density polyethylene dropper.

---

## Additional information

**Entitlement type:**

Marketing Authorisation

---

**Legal basis of product authorisation:**

Hybrid application (Article 13(3) of Directive No 2001/82/EC)

---

**Marketing authorisation holder:**

Chanelle Pharmaceuticals Manufacturing Limited

---

**Marketing authorisation date:**

27/11/2023

---

**Manufacturing sites for batch release:**

Chanelle Pharmaceuticals Manufacturing Limited

---

**Responsible authority:**

Ministry Of Agriculture Veterinary And Food Safety Directorate

---

**Authorisation number:**

UP/I-322-05/23-01/787

---

**Date of authorisation status change:**

27/11/2023

---

**Reference member state:**

Ireland

---

**Procedure number:**

IE/V/0659/001

---

**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

---

To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

Summary of Product Characteristics

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