

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)

Pharmaceutical form:

Cutaneous/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:

Romania

Available in:

Romania

Package description:

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

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

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

Marketing authorisation holder:

Vetviva Richter GmbH

Marketing authorisation date:

15/04/2015

Manufacturing sites for batch release:

Vetviva Richter GmbH

Responsible authority:

Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:

230049

Date of authorisation status change:

10/02/2025

Reference member state:

Austria

Procedure number:

AT/V/0014/001

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)

To consult adverse reactions on veterinary medicinal products please go to
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