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:
Slovenia

Available in:
Slovenia

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:
11/06/2024

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

Responsible authority:
Agency For Medicinal Products And Medical Devices Of The Republic Of Slovenia

Authorisation number:
DC/V/0810/001

Date of authorisation status change:
11/06/2024

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

Summary of Product Characteristics

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

Package Leaflet

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

Labelling

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

Combined File of all Documents

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