Ototop Ear Drops and Cutaneous Suspension for Dogs, Cats and Guinea Pigs

Authorised

- POLYMYXIN B SULFATE
- Prednisolone acetate
- Miconazole nitrate

Product identification

Medicine name:
Ototop Ear Drops and Cutaneous Suspension for Dogs, Cats and Guinea Pigs
Ototop (23 mg + 5 mg + 5500 IU)/ml Krople do uszu i zawiesina na skórę

Active substance:
POLYMYXIN B SULFATE
Prednisolone acetate
Miconazole nitrate

Target species:
Dog
Cat
Guinea pig

Route of administration:
Cutaneous use
Auricular use

Product details

Active substance and strength:
POLYMYXIN B SULFATE
0.53 milligram(s) / 1.00 millilitre(s)

Prednisolone acetate
5.00 milligram(s) / 1.00 millilitre(s)

Miconazole nitrate
23.00 milligram(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:
Poland

Package description:
(ID3) 100 millilitre(s): Box (Cardboard) with 1 Bottle (Low Density PolyEthylene) with 100 millilitre(s), closed with Screw cap (PolyPropylene)
(ID2) 30 millilitre(s): Box (Cardboard) with 1 Bottle (Low Density PolyEthylene) with 30 millilitre(s), closed with Screw cap (PolyPropylene)
(ID1) 15 millilitre(s): Box (Cardboard) with 1 Bottle (Low Density PolyEthylene) with 15 millilitre(s), closed with Screw cap (PolyPropylene)

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:
Industrial Veterinaria S.A.

Marketing authorisation date:
31/07/2020

Manufacturing sites for batch release:
Industrial Veterinaria S.A.
aniMedica Herstellungs GmbH
aniMedica GmbH

Responsible authority:
Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

Authorisation number:
3001

Date of authorisation status change:
31/07/2020

Reference member state:
Germany

Procedure number:
DE/V/0321/001

Concerned member states:
Austria Belgium Cyprus Czechia Estonia Greece Hungary Italy Latvia Lithuania Malta Poland Portugal Romania Slovakia Slovenia Spain

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.