

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

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

5500.00 international unit(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:

Estonia

Available in:

Estonia

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:

4/05/2020

Manufacturing sites for batch release:

Industrial Veterinaria S.A.
aniMedica Herstellungs GmbH
aniMedica GmbH

Responsible authority:

State Agency Of Medicines

Authorisation number:

2236

Date of authorisation status change:

4/05/2020

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.

Combined File of all Documents

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