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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

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Authorisation status:
Valid

Authorised in:
Malta

Available in:
Malta

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:
13/08/2020

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

Responsible authority:
Veterinary And Phytosanitary Regulation Department

Authorisation number:
VMA96

Date of authorisation status change:
13/08/2020

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

Combined File of all Documents

2402648-paren-20210713.pdf