

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 ušné kvapky a kožná suspenzia pre psy, mačky a morčatá

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

Withdrawal period by route of administration:

Cutaneous use:

-

Dog

-

Cat

-

Guinea pig

Auricular use:

-

Dog

-

Cat

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QS02CA01

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Slovakia

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:

9/07/2020

Manufacturing sites for batch release:

Industrial Veterinaria S.A.

aniMedica Herstellungs GmbH

aniMedica GmbH

Responsible authority:

Institute For State Control Of Veterinary Biologicals And Medicaments

Authorisation number:

96/018/DC/20-S

Date of authorisation status change:

9/07/2020

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

Combined File of all Documents

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