Otisur

Authorised

- Miconazole nitrate
- Prednisolone acetate
- POLYMYXIN B SULFATE

Product identification

Medicine name:
Otisur
Orilane, 23,0 mg/ml + 5,0 mg/ml + 5500 RÜ/ml kõrvatilgad, suspensioon kassidele ja koertele

Active substance:
Miconazole nitrate
Prednisolone acetate
POLYMYXIN B SULFATE

Target species:
Dog
Cat

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:
Estonia

Package description:
Available only in Estonian
Available only in Estonian

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:
Chanelle Pharmaceuticals Manufacturing Limited

Marketing authorisation date:
3/09/2023

Manufacturing sites for batch release:
Chanelle Pharmaceuticals Manufacturing Limited

Responsible authority:
State Agency Of Medicines

Authorisation number:
1125223

Date of authorisation status change:
3/09/2023

Reference member state:
Ireland

Procedure number:
IE/V/0659/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Italy Latvia Lithuania Netherlands Norway Poland Portugal Romania Slovenia Spain Sweden

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

English (PDF)

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