

Otisor

Authorised

- Miconazole nitrate
- Prednisolone acetate
- POLYMYXIN B SULFATE

Product identification

Medicine name:

Otisor

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:

Denmark

Package description:

30 ml white low-density polyethylene squeeze dropper bottle with a white, high-density polyethylene cap (screw fit), and a white, low-density polyethylene dropper.
15 ml white low-density polyethylene squeeze dropper bottle with a white, high-density polyethylene cap (screw fit), and a white, low-density polyethylene dropper.

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:

7/02/2023

Manufacturing sites for batch release:

Chanelle Pharmaceuticals Manufacturing Limited

Responsible authority:

Danish Medicines Agency

Authorisation number:

65924

Date of authorisation status change:

7/02/2023

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