Aurimic Ear Drops and Cutaneous Suspension for Dogs and Cats

Authorised

- Miconazole nitrate
- Prednisolone acetate
- POLYMYXIN B SULFATE

Product identification

Medicine name:
Mitex Ohrentropfen und Suspension zur Anwendung auf der Haut für Hunde und Katzen
Aurimic Ear Drops and Cutaneous Suspension for Dogs and Cats

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:

Cutaneous/ear drops suspension

Withdrawal period by route of administration:

Auricular use:

- **Dog**
- **Cat**

Cutaneous use:

- **Dog**
- **Cat**

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:

United Kingdom (Northern Ireland)

Available in:
United Kingdom (Northern Ireland)

Package description:
Dropper container of white, opaque LDPE with white, opaque HDPE screw cap in a cardboard box. Pack size: 1 x 20 ml

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
Vetviva Richter GmbH

Marketing authorisation date:
5/03/2015

Manufacturing sites for batch release:
Vetviva Richter GmbH

Responsible authority:
The Veterinary Medicines Directorate

Authorisation number:
Vm 57446/4004

Date of authorisation status change:
8/08/2023

Reference member state:
Austria

Procedure number:
AT/V/0014/001

Concerned member states:
Belgium Bulgaria Croatia Czechia Denmark Estonia Finland France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

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

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