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Otoxolan ear drops, suspension for dogs

Authorised

- Marbofloxacin
- Clotrimazole
- Dexamethasone acetate

Product identification

Medicine name:
Otoxolan ear drops, suspension for dogs

Active substance:
Marbofloxacin

Clotrimazole

Dexamethasone acetate

Target species:
Dog

Route of administration:
Auricular use

Product details

Active substance and strength:
Marbofloxacin

3.00 milligram(s) / 1.00 millilitre(s)

Clotrimazole
10.00 milligram(s) / 1.00 millilitre(s)

Dexamethasone acetate
1.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Ear drops, suspension

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QS02CA06

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Poland

Available in:
Poland

Package description:
Available only in Polish
Available only in Polish
Available only in Polish

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:
KRKA tovarna zdravil d.d. Novo mesto

Marketing authorisation date:
31/03/2017

Manufacturing sites for batch release:
TAD Pharma GmbH
KRKA tovarna zdravil d.d. Novo mesto

Responsible authority:
Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

Authorisation number:
2639

Date of authorisation status change:
31/03/2017

Reference member state:
Ireland

Procedure number:
IE/V/0438/001

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

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

Documents

Summary of Product Characteristics

English (PDF)

Published on: 26/08/2024
Updated on: 14/03/2026
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Package Leaflet

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Labelling

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