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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:
Hungary

Available in:
Hungary

Package description:
Box containing 1 x 10 ml LDPE bottle with an LDPE dropper and HDPE screw cap, anda thermoplastic elastomer dropper with cap.
Box containing 1 x 20 ml LDPE bottle with an LDPE dropper and HDPE screw cap, and2 thermoplastic elastomer dropper with cap.
Box containing 1 x 30 ml LDPE bottle with an LDPE dropper and HDPE screw cap, and3 thermoplastic elastomer dropper with cap.

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:
10/11/2016

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

Responsible authority:
Directorate Of Veterinary Medicinal Products

Authorisation number:
This information is not available for this product.

Date of authorisation status change:
10/11/2016

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)

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Documents

Summary of Product Characteristics

English (PDF)
Published on: 26/08/2024
Updated on: 14/03/2026
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