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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:

France

Package description:

Box containing 1 x 10 ml LDPE bottle with an LDPE dropper and HDPE screw cap, and a thermoplastic elastomer dropper with cap.

Box containing 1 x 20 ml LDPE bottle with an LDPE dropper and HDPE screw cap, and 2 thermoplastic elastomer dropper with cap.

Box containing 1 x 30 ml LDPE bottle with an LDPE dropper and HDPE screw cap, and 3 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:

18/11/2016

Manufacturing sites for batch release:

KRKA tovarna zdravil d.d. Novo mesto
TAD Pharma GmbH

Responsible authority:

French Agency For Food, Environmental And Occupational Health & Safety

Authorisation number:

FR/V/8243893 5/2016

Date of authorisation status change:

22/12/2021

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

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Package Leaflet and Labelling

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