Otoxolan ear drops, suspension for dogs

Authorised

- Dexamethasone acetate
- Clotrimazole
- Marbofloxacin

Product identification

Medicine name:
Otoxolan ear drops, suspension for dogs
OTOXOLAN GOTAS OTICAS EN SUSPENSION PARA PERROS

Active substance:
Dexamethasone acetate

Clotrimazole

Marbofloxacin

Target species:
Dog

Route of administration:
Auricular use

Product details

Active substance and strength:
Dexamethasone acetate
1.00 milligram(s) / 1.00 millilitre(s)

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

Marbofloxacin
3.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Ear drops, suspension

Withdrawal period by route of administration:

Auricular use:

- **Dog**

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QS02CA06

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

Authorisation status:
Valid

Authorised in:
Spain

Package description:
Box containing 1 x 30 ml LDPE bottle with an LDPE dropper and HDPE screw cap, and3 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 10 ml LDPE bottle with an LDPE dropper and HDPE screw cap, anda 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:
16/11/2016

Manufacturing sites for batch release:
Tad Pharma GmbH
Krka d.d. Novo Mesto

Responsible authority:
The Spanish Agency Of Medicines And Medical Devices

Authorisation number:
3501 ESP

Date of authorisation status change:
19/02/2019

Reference member state:
Ireland

Procedure number:
IE/V/0438/001

Concerned member states:
Austria Belgium Bulgaria Croatia Czechia Denmark Estonia France Germany Greece 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: 8/03/2023
Download

Package Leaflet

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Labelling

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