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:
Denmark

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:
11/11/2016

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

Responsible authority:
Danish Medicines Agency

Authorisation number:
57253

Date of authorisation status change:
11/11/2016

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)

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

Documents

Summary of Product Characteristics

English (PDF)

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