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Cefenidex CA/DEX 2 mg/ml + 1 mg/ml eye drops, solution for dogs and cats

Authorised

- Dexamethasone sodium phosphate
- Chloramphenicol

Product identification

Medicine name:
Cefenidex CA/DEX 2 mg/ml + 1 mg/ml eye drops, solution for dogs and cats

Active substance:
Dexamethasone sodium phosphate
Chloramphenicol

Target species:
Dog
Cat

Route of administration:
Ocular use

Product details

Active substance and strength:
Dexamethasone sodium phosphate

1.32 milligram(s) / 1.00 millilitre(s)

Chloramphenicol
2.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Eye drops, solution

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QS01CA01

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

Authorisation status:
Valid

Authorised in:
Denmark

Available in:
Denmark

Package description:
(ID1) 10 millilitre(s): Box (Cardboard) with 1 Bottle (Low Density PolyEthylene) with 10 millilitre(s), closed with Screw cap (High Density PolyEthylene)

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Hybrid application – bioavailability studies cannot be used to demonstrate bioequivalence (Article 19(1)(b) of Regulation (EU) 2019/6)

Marketing authorisation holder:
CP-Pharma Handelsgesellschaft mbH

Marketing authorisation date:
11/09/2024

Manufacturing sites for batch release:
CP-Pharma Handelsgesellschaft mbH

Responsible authority:
Danish Medicines Agency

Authorisation number:
71510

Date of authorisation status change:
11/09/2024

Reference member state:
Germany

Procedure number:
DE/V/0343/001

Concerned member states:
Austria Belgium Denmark Estonia Finland France Greece Hungary Ireland Italy Latvia Lithuania Netherlands Norway Poland Portugal Spain Sweden United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

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Combined File of all Documents

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