

Cepfenidex 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

Cepfenidex 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:

Ireland

Package description:

(ID1) 10 millilitre(s): Box (board) with 1 Bottle (low-density polyethylene) with 10 millilitre(s), closed with Schraubdeckel (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:

30/08/2024

Manufacturing sites for batch release:

CP-Pharma Handelsgesellschaft mbH

Responsible authority:

Health Products Regulatory Authority

Authorisation number:

VPA10810/036/001

Date of authorisation status change:

30/08/2024

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

Combined File of all Documents

2402484-paren-20240710.pdf