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Uriphex 50 mg/ml, oral solution for dogs

Authorised

- Phenylpropanolamine hydrochloride

Product identification

Medicine name:
Uriphex 50 mg/ml, oral solution for dogs

Active substance:
Phenylpropanolamine hydrochloride

Target species:
Dog (bitch)

Route of administration:
Oral use

Product details

Active substance and strength:
Phenylpropanolamine hydrochloride
50.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Oral solution

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QG04BX91

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

Authorisation status:
Valid

Authorised in:
Denmark

Package description:
HDPE bottle closed with white polypropylene child-resistant cap and LDPE syringe adaptor. A 1 mL HDPE/polypropylene graduated syringe is supplied with each bottle. Bottle of 30 mL.
HDPE bottle closed with white polypropylene child-resistant cap and LDPE syringe adaptor. A 1 mL HDPE/polypropylene graduated syringe is supplied with each bottle. Bottle of 60 mL.
HDPE bottle closed with white polypropylene child-resistant cap and LDPE syringe adaptor. A 1 mL HDPE/polypropylene graduated syringe is supplied with each bottle. Bottle of 100 mL.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 18 of Regulation (EU) 2019/6)

Marketing authorisation holder:
Alfasan Nederland B.V.

Marketing authorisation date:
4/07/2024

Manufacturing sites for batch release:
Alfasan Nederland B.V.

Responsible authority:
Danish Medicines Agency

Authorisation number:
67602

Date of authorisation status change:
4/07/2024

Reference member state:
Netherlands

Procedure number:
NL/V/0383/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

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Documents

Summary of Product Characteristics

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Combined File of all Documents