Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A PROPOSED VETERINARY MEDICINAL PRODUCT

Uriphex, Oral Solution for Dogs

Date Created: December 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Uriphex, Oral Solution for Dogs
Applicant	Alfasan Nederland B.V. Kuipersweg 9 3449 JA Woerden The Netherlands
Active substance	Phenylpropanolamine Hydrochloride
ATC Vetcode	QG04BX91
Target species	Dogs
Indication for use	For the treatment of urinary incontinence associated with urethral sphincter incompetence in the bitch. Efficacy has only been demonstrated in ovariohysterectomised bitches.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 31(1) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	11/10/2023

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Propalin 40mg/ml Syrup for dogs.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains phenylpropanolamine hydrochloride 50mg/ml and the excipients sorbitol.

The container/closure system consists of HDPE bottles with a child resistant closure and a 1ml dosing syringe. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative are justified.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of heating, mixing and filling.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

II.C. Control of Starting Materials

The active substance is phenylpropanolamine hydrochloride an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable

II.E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product. Satisfactory validation data for the analytical methods have been provided. Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification. Control tests on the finished product are appropriate to adequately control the quality of the pharmaceutical from.

II.F. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 3 years Shelf life after first opening the immediate packaging: 3 months.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

As this is a generic application in accordance with Article 13(1) of the Directive 2001/82/EC as amended, the bioequivalence with a reference product has been demonstrated, results of pharmaco-toxicological tests are not required.

Toxicological Studies

Not applicable due to the legal basis of the product

User Safety

A user risk assessment was provided in compliance with the relevant guidelines.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore, the following applicant's user recommendations are appropriate:

- Phenylpropanolamine hydrochloride is toxic when ingested at higher doses. Side effects may include dizziness, headache, nausea, insomnia or restlessness, and increased blood pressure.
- High overdose may be fatal, especially in children. Avoid oral ingestion including hand-to-mouth contact.
- To avoid accidental ingestion this medicinal product should be used and stored out of the sight and reach of children. Always close the cap tightly after use to ensure the child-resistant closure works correctly. Do not leave a filled syringe unattended.
- In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
- Wash hands after handling the veterinary medicinal product.
- This veterinary medicinal product may cause eye irritation. Avoid eye contact. In case of accidental eye contact, rinse the eye thoroughly with clean water and consult a physician if irritation persists.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:
The product will only be used in non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required.

IV. CLINICAL DOCUMENTATION

As this is a generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics the benefit/risk profile of the product is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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