

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UripheX, oral solution for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Phenylpropanolamine 40.28 mg
(equivalent to 50 mg phenylpropanolamine hydrochloride)

Excipients:

Qualitative composition of excipients and other constituents

Sorbitol 70 %, liquid (non-crystallising)

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Solution

A colourless to yellow/brownish viscous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indication for use, specifying the target species

For the treatment of urinary incontinence associated with urethral sphincter incompetence in the bitch. Efficacy has only been demonstrated in ovariectomised bitches.

4.3 Contraindications

Do not use in animals treated with non-selective monoamine oxidase inhibitors.
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

In bitches less than 1 year old, the possibility of anatomical conditions contributing to incontinence should be considered before treatment is initiated.

The use of the product is not appropriate for the treatment of behavioral causes of inappropriate urination.

4.5 Special precautions for use

i) Special precautions for safe use in animals

Because phenylpropanolamine is a sympathomimetic agent, it may affect the cardiovascular system, especially blood pressure and heart rate, and should therefore be used with caution in animals with cardiovascular disease.

Administration to dogs with hyperthyroidism should be made with caution as the risk of arrhythmias is increased.

Caution should be exercised when treating animals with severe renal or hepatic insufficiency, diabetes mellitus, hyperadrenocorticism, glaucoma or other metabolic disorders.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Phenylpropanolamine hydrochloride is toxic when ingested in 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, the veterinary 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.

People with known hypersensitivity (allergy) to phenylpropanolamine hydrochloride should avoid contact with the veterinary medicinal product. Wear gloves. If allergic symptoms develop, such as a skin rash, swelling of the face, lips or eyes or difficulty in breathing, you should seek medical attention immediately and show the package leaflet or label to the physician.

Special precautions for the protection of the environment:

Not applicable.

iii) Other precautions

Not applicable.

4.6 Adverse events (frequency and seriousness)

Dogs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity
Undetermined frequency (cannot be estimated from the available data):	Restlessness Arrhythmia*, high blood pressure**, increased heart rate** Diarrhoea*, loose stool* Dizziness Collapse*, Appetite loss*

*In clinical trials treatment was continued depending on severity of the undesirable effect observed.

**Effects on heart rate and blood pressure are a result of excessive stimulation of the sympathetic nervous system.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorization holder or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

4.7 Use during pregnancy and lactation

Do not use in pregnant or lactating bitches.

No data are available on the effect of phenylpropanolamine hydrochloride on the reproductive functions of females.

4.8 Interaction with other medicinal products and other forms of interaction

Caution should be exercised when this veterinary medicinal product is administered with other sympathomimetic drugs, anticholinergic drugs, tricyclic antidepressants or specific type B monoamine oxidase.

In combination with some anesthetics (cyclopropane, halothane), thiobarbiturates and digitalis derivatives, the risk of arrhythmias may increase.

4.9 Amount(s) to be administered and administration route

Oral use.

The recommended dose of phenylpropanolamine hydrochloride is 1 mg/kg bodyweight 3 times daily in the feed, corresponding to 0.1 ml of the veterinary medicinal product per 5 kg bodyweight 3 times daily.

The absorption rate is increased if the product is administered to fasted dogs.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In healthy dogs, no side effects were observed up to 5 times the recommended dose. However, an overdose may produce symptoms of excessive stimulation of the sympathetic nervous system. Treatment should be symptomatic. Alpha-blockers may be effective in the event of a severe overdose.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sympaticomimetics

ATCvet code: QG04BX91

5.1 Pharmacodynamics

Phenylpropanolamine is a racemic mixture of D and L enantiomers. Phenylpropanolamine hydrochloride is a sympathomimetic agent which acts by direct stimulation of the smooth muscle of the internal urethral sphincter. It is an analogue of the endogenous sympathomimetic amines.

Phenylpropanolamine hydrochloride has weak sympathomimetic activity and produces a wide range of pharmacological effects. It appears to act directly on the smooth muscle of the lower urinary tract. The smooth muscle is thought to be largely responsible for the maintenance of tone in the resting state.

The clinical effect of phenylpropanolamine in urinary incontinence is based on its stimulation effect on α -adrenergic receptors. This causes an increase in, and a stabilisation of, the closure pressure in the urethra, which is innervated mainly by adrenergic nerves.

5.2 Pharmacokinetics

In the dog, the mean half-life of phenylpropanolamine is approximately 3 hours with maximum plasma concentrations being reached after approximately 1 hour. No accumulation of phenylpropanolamine was observed after a dose of 1 mg/kg 3 times daily for 15 days.

When the veterinary medicinal product is administered to a fasted dog, the bioavailability increases significantly.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol, liquid (non crystallising)

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

Shelf life after first opening the immediate packaging: 3 months

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

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.

Package sizes:

Bottle of 30 mL

Bottle of 60 mL

Bottle of 100 mL

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste material derived from the use of the veterinary medicinal product

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

Kuipersweg 9

3449 JA Woerden

The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 36408/5017

9. DATE OF FIRST AUTHORISATION

11 October 2023

10. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

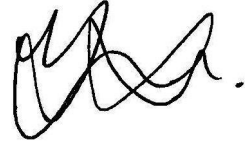
October 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 11 October 2023