[Version 9, 11/2022]

# ANNEX I

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uriphex 50 mg/ml, oral solution for dogs
(NL/AT/BE/BG/HR/CY/CZ//DE/EL/HU/IT/LV/LT/LU/PL/PT/RO/SK/SI/ES)
Uriphex 50 mg/ml oral solution for dogs (EE)
Uriphex Vet 50 mg/ml, oral solution for dogs (DK/NO/SE/FI/IS)
Uriphex, oral solution for dogs (FR/IE/UKNI)

## 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, liquid (non-crystallising) |

A colourless to yellow-brownish viscous oral solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dog (bitch).

### 3.2 Indication for use for each target species

Treatment of urinary incontinence associated with urethral sphincter incompetence in the bitch.
Efficacy has only been demonstrated in ovariohysterectomised bitches

### 3.3 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.

### 3.4 Special warnings

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.

## 3.5 Special precautions for use

Special precautions for safe use in the target species

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.

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

Phenylpropanolamine hydrochloride is toxic when ingested at higher doses. Adverse effects may include dizziness, headache, nausea, insomnia or restlessness, and increased blood pressure. Higher doses 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.

## 3.6 Adverse events

Dogs

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Hypersensitivity |
| Undetermined frequency (cannot be estimated from the available data): | Restlessness<br>Arrhythmia*, high blood pressure**, increased heart rate**<br>Diarrhoea*, loose stool*<br>Dizziness<br>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 package leaflet for respective contact details.

**3.7 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.

**3.8 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.

**3.9 Administration routes and dosage**

Oral administration of 3 mg phenylpropanolamine hydrochloride per kg body weight per day divided over 2 or 3 administrations for 3 to 4 weeks.

When the symptoms return, the treatment can be restarted.

Dosing table with examples:

| | individual dose (ml) | | | individual dose (ml) | |
|---|---|---|---|---|---|
| **kg bodyweight** | twice daily | three times daily | **kg bw** | twice daily | three times daily |
| **2** | 0.06 | | **32** | 0.96 | 0.64 |
| **4** | 0.12 | 0.08 | **34** | 1.02 | 0.68 |
| **6** | 0.18 | 0.12 | **36** | 1.08 | 0.72 |
| **8** | 0.24 | 0.16 | **38** | 1.14 | 0.76 |
| **10** | 0.3 | 0.2 | **40** | 1.2 | 0.8 |
| **12** | 0.36 | 0.24 | **42** | 1.26 | 0.84 |
| **14** | 0.42 | 0.28 | **44** | 1.32 | 0.88 |
| **16** | 0.48 | 0.32 | **46** | 1.38 | 0.92 |
| **18** | 0.54 | 0.36 | **48** | 1.44 | 0.96 |
| **20** | 0.6 | 0.4 | **50** | 1.5 | 1 |
| **22** | 0.66 | 0.44 | **52** | 1.56 | 1.04 |
| **24** | 0.72 | 0.48 | **54** | 1.62 | 1.08 |
| **26** | 0.78 | 0.52 | **56** | 1.68 | 1.12 |
| **28** | 0.84 | 0.56 | **58** | 1.74 | 1.16 |
| **30** | 0.9 | 0.6 | **60** | 1.8 | 1.2 |

To ensure a correct dosage, body weight should be determined as accurately as possible
In the case of two daily administrations, the dog should weigh at least 1.6 kg. In the case of three daily administrations, the dog should weigh at least 2.5 kg.

**3.10 Symptoms of overdose (symptoms, emergency procedures, antidotes)**

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.

**3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable.

**3.12 Withdrawal period(s)**

Not applicable.

## 4. PHARMACOLOGICAL INFORMATION

**4.1 ATCvet code:** QG04BX91

### 4.2 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.

### 4.3 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.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

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

### 5.2 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

### 5.3 Special precautions for storage

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

### 5.4 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.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste material resulting from the use of the veterinary medicinal product

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORIZATION HOLDER

Alfasan Nederland B.V.

## 7. MARKETING AUTHORIZATION NUMBER(S)

## 8. DATE OF FIRST AUTHORISATION

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary