

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UripheX, oral solution for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Phenylpropanolamine 40.28 mg
(equivalent to 50 mg phenylpropanolamine hydrochloride)

3. PACKAGE SIZE

30 ml
60 ml
100 ml

4. TARGET SPECIES

Dogs (bitch).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/3020

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Bottle 60ml/100ml/ HDPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UripheX, oral solution for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Phenylpropanolamine 40.28 mg
(equivalent to 50 mg phenylpropanolamine hydrochloride)

3. TARGET SPECIES

Dogs (bitch).

4. ROUTES OF ADMINISTRATION

Oral use

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.

7. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Bottle 30ml /HDPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uriphex

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Phenylpropanolamine 40.28 mg
(equivalent to 50 mg phenylpropanolamine hydrochloride)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

UripheX, oral solution for dogs

2. 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. Target species

Dog (bitch).

4. Indications for use

Treatment of urinary incontinence associated with urethral sphincter incompetence in the bitch.

Efficacy has only been demonstrated in ovariohysterectomised bitches.

5. 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.

6. Special warnings

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.

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.

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.

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.

Overdose:

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.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

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

7. Adverse events

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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

Dosing table with examples:

kg bodyweight	individual dose (ml)		kg bw	individual dose (ml)	
	twice daily	three times daily		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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle after Exp. The expiry date refers to the last day of that month. Shelf life after first opening the immediate packaging: 3 months.

12. Special precautions for disposal

For UK-GB/NI only (in the mock up phase): Medicines should not be disposed of via wastewater.

For other MS (in the mock up phase): 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

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.

Vm 36408/3020

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Alfasan Nederland B.V.

Kuipersweg 9

3449 JA Woerden

The Netherlands

Tel.: +31 348 41 69 45

Local representatives and contact details to report suspected adverse reactions:

To be completed nationally. There may be national differences in the designated contact point for the reporting of suspected adverse events (MAH or local representative) which can be reflected accordingly in each national translation. If the MAH is the local contact point, contact details to report suspected adverse reactions will include a telephone number (Tel: +31 348 41 69 45), therefore it is now -grey shaded.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

United Kingdom (Northern Ireland)

{Name}

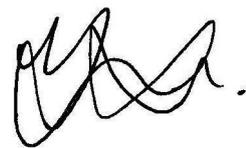
<{Address}

{Town} {Postal code} – UK>

Tel: + {Telephone number}

<{E-mail}>>

17. OTHER INFORMATION



Approved: 11 October 2023