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 AND OTHER 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.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.
Once opened, use by. . .

9. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.
Keep the bottle in the outer carton.

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.
Kuipersweg 9
3449 JA Woerden
The Netherlands

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/5017

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V To be supplied only on veterinary prescription

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 AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Phenylpropanolamine 40.28 mg
(equivalent to 50 mg phenylpropanolamine hydrochloride)

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Oral use
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions

Once opened, use within 3 months.

Once opened, use by. . .

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

60 ml
100 ml

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

14. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only

POM-V To be supplied only on veterinary prescription

15. MARKETING AUTHORISATION NUMBERS

Vm 36408/5017

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Bottle, 30 ml / HDPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uriphex

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Each ml contains:

Active substance:
Phenylpropanolamine 40.28 mg
(equivalent to 50 mg phenylpropanolamine hydrochloride)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}

Once opened, use by. . .

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

6. ROUTE(S) OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Uriphex, oral solution for dogs

2. Composition

Phenylpropanolamine 40.28 mg/ml
(equivalent to 50 mg phenylpropanolamine hydrochloride/ml)

Sorbitol 70 %, liquid (non-crystallising)

A colourless to yellow/brownish viscous solution.

3. Target species

Dogs.

4. Indications for use

For the treatment of urinary incontinence associated with urethral sphincter incompetence in the bitch. Efficacy has only been demonstrated in ovariohysterectomised (spayed) 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. 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.

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 mixed with other veterinary medicinal products.

For Animal Treatment Only

Keep out of sight and reach of children

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 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.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.

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.
Once the bottle is opened, using the shelf-life after first opening, calculate the discard date and record in the space provided

12. Special precautions for disposal

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.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.
These measures should help to protect the environment.

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

Vm 36408/5017

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}
Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

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

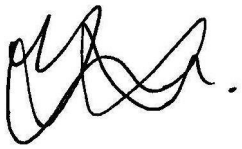
Local representatives and contact details to report suspected adverse reactions:

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

United Kingdom (Great Brittain)
Anupco Ltd.
Lodge House, Lodge Park,
Lodge Lane, Langham, Colchester,
Essex, CO4 5NE

Tel: +44 (0) 1206 233528
Email sales@kela.health

17. OTHER INFORMATION



Approved: 11 October 2023