[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uristop 40 mg/ml syrup for dogs [ES, PT]
Urixine 40 mg/ml syrup for dogs [NL, BE, DE, PL, LT, LV, RO, AT, CZ, SK, NI(UK), IT]
Urixine 40.28 mg/ml syrup for dogs [FR]
Urixine [EE]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Phenylpropanolamine.....40.28 mg
(equivalent to 50 mg of Phenylpropanolamine hydrochloride).

Excipient:

Qualitative composition of excipients and other constituents
Sorbitol, liquid non crystallising

Clear colorless or slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not administer to patients treated with non-selective monoamine oxidase inhibitors.
Do not use in cases of hypersensitivity to the active substance or the excipient.

3.4 Special warnings

The use of the veterinary medicinal product is not appropriate for the treatment of behavioural causes of inappropriate urination.
In bitches less than 1 year old the possibility of anatomical disorders contributing to incontinence should be considered prior to treatment.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Phenylpropanolamine, a sympathomimetic drug, may affect the cardiovascular system, especially blood pressure and heart rate, and should be used with caution in animals with cardiovascular diseases.

Care should be exercised in treating animals with severe renal or hepatic insufficiency, diabetes mellitus, hyperadrenocorticism, glaucoma, hyperthyroidism 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 in 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 skin and eye irritation. Avoid skin and eye contact.
In case of accidental skin contact, wash the contaminated area with soap and water.
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

Rare (more than 1 but less than 10 animals in 10,000 animals treated)	Loose stools[1], liquid diarrhoea[1] Emesis, lethargy
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Decreased appetite[1], collapse Dizziness, ataxia Increased blood pressure, increased heart rate, Arrhythmia[1] Hyperactivity (including restlessness), aggression Polyuria, polydipsia Hypersensitivity reaction Seizure

[1]Treatment can be continued depending on the severity of the undesirable effect observed.

Sympathomimetics can produce a wide variety of effects, many of which mimic the reactions of excessive stimulation of the sympathetic nervous system which can induce proteinuria.

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 authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use during pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Care should be exercised in administering the veterinary medicinal product with other sympathomimetic drugs, anticholinergic drugs, tricyclic antidepressants or specific type B monoamine oxidase inhibitors.

3.9 Administration routes and dosage

Oral use.

The recommended dose is 1 mg of phenylpropanolamine/kg b.w. 3 times a day, with food (equivalent to 0.1 ml of veterinary medicinal product for every 5 kg b.w. 3 times a day).

Absorption of the veterinary medicinal product is increased when administered to dogs in an empty stomach.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In healthy dogs, no side effects were observed at up to 5 times the recommended dosage. However, an overdose of phenylpropanolamine could produce symptoms of excessive stimulation of the sympathetic nervous system. Treatment should be symptomatic. Alpha-adrenergic blockers may be appropriate in the case of severe overdose. However, no specific recommendation on drugs or dosages can be given.

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 periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QG04BX91.

4.2 Pharmacodynamics

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.
Phenylpropanolamine is a racemic mixture of D and L enantiomers.

4.3 Pharmacokinetics

In the dog, the mean half-life of Phenylpropanolamine is approximately 3 hours with maximal plasma concentrations being found after approximately 1 hour.
No accumulation of phenylpropanolamine has been observed after a dose of 1 mg/kg 3 times daily over 15 days.

When the veterinary medicinal product is administered to a fasted dog, bioavailability is increased 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: 2 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

High density polyethylene bottle, with dosing syringe adaptor in low density polyethylene and childproof polypropylene / expanded polyethylene safety lock. The packaging contains a 1.5 ml low density polyethylene / polystyrene dosing syringe with 0.1 ml subdivisions.

Package size:
Box with a 50 ml bottle and a dosing syringe
Box with a 100 ml bottle and a dosing syringe

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 AUTHORISATION HOLDER

LABORATORIOS KARIZOO, S.A.

7. MARKETING AUTHORISATION 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).