SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Continence 40 mg/ml syrup for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
phenylpropanolamine 40.28 mg equivalent to phenylpropanolamine hydrochloride 50 mg

Excipients:

Qualitative composition of excipients and other constituents
liquid sorbitol (non crystallising)

Clear colourless to pale yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the management of urinary incontinence associated with urethral sphincter incompetence in the bitch, particularly that associated with ovariohysterectomy.

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 to any of the excipients.
Do not administer to pregnant or lactating bitches.

3.4 Special warnings

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

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.
Accidental ingestion by a child may be fatal.
To avoid accidental ingestion, the veterinary medicinal product must be used and kept out of sight and reach of children. Always replace the cap securely after use and store the syringe and bottle inside the cardboard box at all times.
In case of accidental ingestion, seek medical attention immediately and show the package leaflet or the label to the physician.
In the event of accidental skin contact, wash the contaminated area with soap and water. 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 for about 15 minutes and consult a physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction.
Undetermined frequency (cannot be estimated from the available data):	Loose stool; Diarrhoea; Decreased appetite; Arrhythmia; Collapse. Dizziness; Aggression; Restlessness.

*Sympathomimetics may produce a wide range of effects, most of which mimic the results of excessive stimulation of the sympathetic nervous system (e.g. effects on heart rate and blood pressure).

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 the whole or part of the pregnancy and lactation).

3.8 Interaction with other medicinal products and other forms of interaction

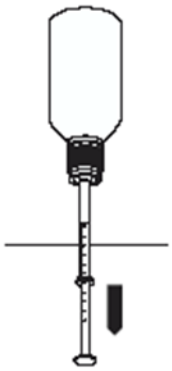
Care should be exercised in administering the veterinary medicinal product with other sympathomimetic drugs, anticholinergic drugs, tricyclic antidepressants or specific type B monoamine oxidase inhibitors.

3.9 Administration routes and dosage

For oral use.
The recommended dose of phenylpropanolamine is 1.5 mg/kg bodyweight (equivalent to 0.15 ml per 5 kg bodyweight) twice daily in the feed. Alternatively, 1 mg/kg bodyweight (equivalent to 0.1 ml per 5 kg bodyweight) may be administered three times daily in the feed. The absorption rate is increased if the veterinary medicinal product is administered to fasted dogs.

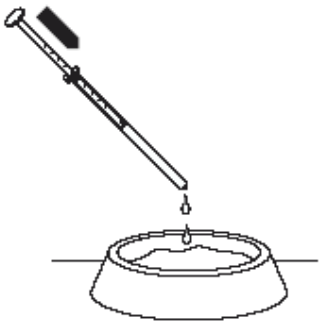
1. Remove the child-proof security cap by pressing firmly down and rotating anticlockwise.

2. Take the dosing syringe with the piston all the way down and insert the tip into the dosing syringe adaptor. Firmly push down.



3. Invert the bottle and, holding the syringe, pull the piston downwards aspiring the product slowly into the dosing syringe, to avoid the formation of air bubbles. Stop at the mark shown on the plunger corresponding to the required volume of the product.

4. Straighten the bottle and grasp the lower part of the syringe, close to the neck of the bottle. Remove the dosing syringe from the bottle by turning carefully.



5. Hold the dosing syringe on top of the dog's food and push the piston to the bottom to ensure delivery of the full dose of the product.

6. Replace the cap on the bottle and screw clockwise to close. Keep the bottle out of sight and reach of children.

7. Dry the tip with a clean cloth or paper. Wash the dosing syringe by removing the piston and rinse the items with hot water.	**8**. Dry carefully, making sure that the inside of the syringe is dry before reinserting the piston. Store the syringe inside the cardboard box to avoid access by children.

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

Lethargy and inappetence have been reported following an overdose of 2.5 mg/kg 3 times daily.
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.

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 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 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

None known.

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.
Keep the bottle and the syringe in the outer carton.

5.4 Nature and composition of immediate packaging

50 ml and 100 ml high-density polyethylene (HDPE) bottle with a low-density polyethylene (LDPE) dosing syringe adaptor and a child-resistant screw-cap in polypropylene, in a cardboard box.
The cardboard box contains 1.5 ml LDPE/polystyrene dosing syringe.

Pack-sizes:
Cardboard box with 1 bottle of 50 ml + 1.5 ml dosing syringe
Cardboard box with 1 bottle of 100 ml + 1.5 ml dosing syringe

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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

FATRO S.p.A.

7. MARKETING AUTHORISATION NUMBER

Vm 11557/5008

8. DATE OF FIRST AUTHORISATION

09 August 2019

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

October 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 06 February 2025