Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

CONTINENCE 40 mg/ml syrup for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:

Phenylpropanolamine	40.28	mg
equivalent to phenylpropanolamine hydrochloride	50	mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup.
Clear colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not administer to patients 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.
Do not administer to pregnant or lactating bitches.

4.4 Special warnings for each target species

The 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 product is not appropriate for the treatment of behavioural causes of inappropriate urination.

4.5 Special precautions for use

Special precautions for use in animals
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 overdoses are ingested. 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 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 use of the product.
In the event of accidental eye contact, rinse the eye with clean water for about 15 minutes and seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

In the course of field clinical trials, loose stools, liquid diarrhoea, decrease in appetite, arrhythmia and collapse were reported in some dogs. Treatment was continued depending on the severity of the undesirable effect observed.
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).
Dizziness, aggressiveness and restlessness have been noted in some dogs following treatment. Hypersensitivity may occur in very rare cases.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant or lactating bitches.

4.8 Interaction with other medicinal products and other forms of interactions

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

4.9 Amounts to be administered and administration route

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 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 in a safe place, at room temperature, 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Genito-urinary system and sex hormones, urologicals, phenylpropanolamine
ATC vet code: QG04BX91

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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 product is administered to a fasted dog, bioavailability is increased significantly.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid sorbitol (non crystallising)

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after the first opening of the immediate packaging: 3 months.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Keep the container tightly closed and store the bottle and syringe inside the cardboard box at all times.

6.5 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 and polyethylene.
The cardboard box contains 1.5 ml LDPE/polystyrene dosing syringe.

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

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

7 MARKETING AUTHORISATION HOLDER

FATRO S.p.A.
Via Emilia, 285 - 40064
Ozzano Emilia
Bologna
Italy

8 MARKETING AUTHORISATION NUMBER(S)

VPA10836/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 October 2019

10 DATE OF REVISION OF THE TEXT

January 2020