ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box 50 ml bottle
100 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CONTINENCE 40 mg/ml syrup for dogs
Phenylpropanolamine

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Active substance: Phenylpropanolamine 40.28 mg (equivalent to phenylpropanolamine hydrochloride 50 mg).

3. PHARMACEUTICAL FORM

Syrup

4. PACKAGE SIZE

50 ml bottle + 1.5 ml dosing syringe
100 ml bottle + 1.5 ml dosing syringe

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

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7. METHOD AND ROUTE OF ADMINISTRATION

Oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month /year}
Shelf-life after first opening the container: 3 months
Once opened, use by _____

11. SPECIAL STORAGE CONDITIONS

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.

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

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Fatro S.p.A.
Via Emilia 285
I-40064 Ozzano dell'Emilia BO
Italy

16. MARKETING AUTHORISATION NUMBERS

Vm 11557/4004

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CONTINENCE 40 mg/ml syrup for dogs
Phenylpropanolamine

2. QUANTITY OF ACTIVE SUBSTANCES

1 ml contains:
Phenylpropanolamine 40.28 mg (equivalent to phenylpropanolamine hydrochloride 50 mg).

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

50 ml.

4. ROUTE(S) ADMINISTRATION

For oral use

5. WITHDRAWAL PERIOD

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6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month /year}
Shelf-life after first opening the container: 3 months
Once opened, use by _____

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CONTINENCE 40 mg/ml syrup for dogs
Phenylpropanolamine

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Active substance: Phenylpropanolamine 40.28 mg (equivalent to phenylpropanolamine hydrochloride 50 mg).

3. PHARMACEUTICAL FORM

Syrup

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

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7. METHOD AND ROUTE OF ADMINISTRATION

Oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month /year}
Shelf-life after first opening the container: 3 months
Once opened, use by _____

11. SPECIAL STORAGE CONDITIONS

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.

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

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Fatro S.p.A.
Via Emilia 285
I-40064 Ozzano dell'Emilia BO
Italy

16. MARKETING AUTHORISATION NUMBERS

Vm 11557/4004

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
CONTINENCE
40 mg/ml syrup for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Fatro S.p.A.
Via Emilia 285
I-40064 Ozzano dell'Emilia BO
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CONTINENCE 40 mg/ml syrup for dogs
Phenylpropanolamine

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

1 ml contains:

Active substance:
Phenylpropanolamine……40.28 mg
equivalent to phenylpropanolamine hydrochloride……...50 mg

Syrup.
Clear colourless to pale yellow solution.

4. INDICATIONS

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

5. CONTRAINDICATIONS

Do not administer to patients treated with non-selective monoamine oxidase inhibitors.
Do not use in case of known hypersensitivity to the active substance or to any of the excipients.
Do not administer to pregnant or lactating bitches.

6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

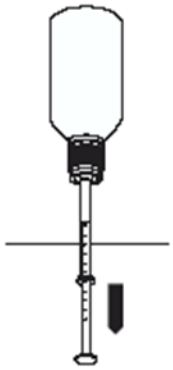
For oral use.
The recommended dose of phenylpropanolamine is 1.5 mg/kg bodyweight (equivalent to 0.15 ml per 5 kg bodyweight) twice daily in the feed. Alternatively, 1 mg/kg bodyweight (equivalent to 0.1 ml per 5 kg bodyweight) may be administered three times daily in the feed. The absorption rate is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

9. ADVICE ON CORRECT ADMINISTRATION

To ensure the correct dosage is administered the body weight of the animals should be determined as accurately as possible to avoid underdosing.

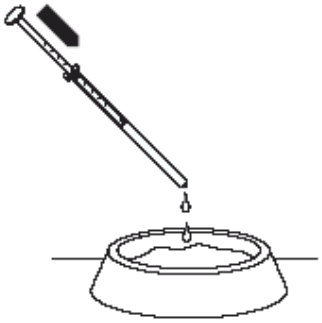
1. Remove the child-proof security cap by pressing firmly down and rotating anticlockwise.

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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out the sight and reach of children.
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.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 3 months.

12. SPECIAL WARNINGS

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.

Special precaution 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 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.

Pregnancy and lactation:
Do not administer to pregnant or lactating bitches.

Interaction with other medicinal products and other forms of interaction
Care should be exercised in administering the product with other sympathomimetic drugs, anticholinergic drugs, tricyclic antidepressants or specific type B monoamine oxidase inhibitors.

Overdose (symptoms, emergency procedures, 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.

Incompatibilities
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

Medicine should not be disposed of via wastewater. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

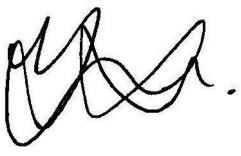
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

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.

Pack size:
50 ml bottle + 1.5 ml dosing syringe
100 ml bottle + 1.5 ml dosing syringe



Approved: 01 August 2023