1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROPALIN Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Phenylpropanolamine Hydrochloride 50 mg

Excipients:

Qualitative composition of excipients and other constituents
Sorbitol solution

A clear syrup.
The colour of the veterinary medicinal product may change from clear to yellow/brown over time. This does not adversely affect the quality of the veterinary medicinal product.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Phenylpropanolamine is a sympathomimetic agent which acts by direct stimulation of the smooth muscle of the internal urethral sphincter. It is indicated in the management of urinary incontinence associated with urethral sphincter incompetence in the bitch, particularly that associated with ovariohysterectomy.

3.3 Contraindications

The use of the veterinary medicinal product is not appropriate for the treatment of behavioural causes of inappropriate urination. Do not use in 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.

3.4 Special warnings

The veterinary medicinal product should be avoided in hypertensive individuals.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Due to the very low doses to be administered, and to avoid any risk of overdose, the animal must be weighed, and the recommended doses must be respected.

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.

In bitches less than 1 year old the possibility of anatomical disorders contributing to incontinence should be considered prior to treatment.

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. High overdose may be fatal, especially in children.

To avoid accidental ingestion, the veterinary medicinal product must be used and kept out of reach of children. Always replace the cap secure after use.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

In case of accidental skin contact, wash the contaminated area with soap and water. Wash hands after use of the veterinary medicinal product.

In case of accidental eye contact, rinse the eye with clean water for about 15 minutes and seek medical advice.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	Diarrhoea[1], loose stool, emesis Lethargy
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Tachycardia[2], hypertension[2], arrhythmia Proteinuria[2], polyuria Wobbliness, ataxia, seizure, collapse Decreased appetite, polydipsia Aggression, hyperactivity (agitation) Hypersensitivity

[1] Liquid.
[2] Effects of sympathomimetics producing excessive stimulation of the sympathetic nervous system.

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

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or fertility. There are no associated clinical studies in humans.

Pregnancy:

Do not use during pregnancy.

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.

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

The recommended dose of phenylpropanolamine is 1.5 mg/kg bodyweight twice daily. This dosage may be measured in an oral syringe at a rate of 0.15 ml per 5 kg bodyweight twice daily in the feed.

Alternatively, 1 mg/kg bodyweight 3 times daily may be given and can be measured in an oral syringe at a rate of 0.1 ml per 5 kg bodyweight 3 times daily in the feed.

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

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

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QG04BX91.

4.2 Pharmacodynamics

Phenypropanolamine hydrochloride is a sympathomimetic agent. 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.

4.3 Pharmacokinetics

The pharmacokinetic properties of Phenylpropanolamine Hydrochloride have not been studied in the dog. In man, the mean half-life of Phenylpropanolamine is about 5 hours with maximal plasma

concentrations being found after about 2.5 hours. Phenylpropanolamine is eliminated in the urine with no appreciable metabolism, the elimination half-life being about 3 hours.

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.

5.3 Special precautions for storage

Do not store above 25 ℃.

Keep the bottle in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

HDPE bottle with LDPE syringe adapter insert and a polypropylene child resistant closure; the package contains also one 1.5 ml graduated syringe of LDPE/polystyrene.

Package sizes:

Cardboard box with 1 bottle of 30 ml with a syringe of 1.5 ml.
Cardboard box with 1 bottle of 100 ml with a syringe of 1.5 ml.

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

Vetoquinol S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10521/033/001

8. DATE OF FIRST AUTHORISATION

14/07/1993

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

19/06/2026

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).