SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROPALIN, 40.28 mg/ml, syrup for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Phenylpropanolamine hydrochloride.....50 mg
(Equivalent to 40.28 mg phenylpropanolamine)

Excipients:

Qualitative composition of excipients and other constituents
Sorbitol solution (70% w/v) non crystallising

Colourless to slightly yellow-brown 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 only been demonstrated in ovariohysterectomised bitches.

3.3 Contraindications

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 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:

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], High blood pressure[2], Arrhythmia Proteinuria[3] Wobbliness, Ataxia, Seizure Decreased appetite Collapse, Polydipsia Aggression, Hyperactivity (agitation) Hypersensitivity Polyuria

[1] *Liquid.*
[2] *Effects of sympathomimetics producing excessive stimulation of the sympathetic nervous system.*
[3] *Due to increased 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 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.

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

The recommended dose for the veterinary medicinal product is 1 mg of phenylpropanolamine hydrochloride for 1 kg bodyweight 3 times daily in the feed, corresponding to 0.1 ml of the veterinary medicinal product / 5 kg bodyweight (i.e., a graduation of the provided syringe for 5 kg), 3 times daily.

The absorption rate is increased if the veterinary medicinal product is administered to fasted dogs.

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

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

Do not store above 25 °C.

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 SA

7. MARKETING AUTHORISATION NUMBER

Vm 06462/3010

8. DATE OF FIRST AUTHORISATION

27 January 1993

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

July 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).

Gavin Hall

Approved: 04 August 2026