

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

PROPALIN , 40.28 mg/ml, syrup for dogs

### 2. Composition

Each ml contains:

#### Active substances:

Phenylpropanolamine.....40.28 mg  
(Equivalent to 50.00 mg phenylpropanolamine hydrochloride)

Colourless to slightly yellow-brown solution.

### 3. Target species

Dogs.



### 4. Indications for use

Treatment of urinary incontinence associated with urethral sphincter incompetence in the bitch.

Efficacy has only been demonstrated in ovariohysterectomised bitches.

### 5. 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.

### 6. Special warnings

#### Special warnings:

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

#### 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 securely 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.

Pregnancy and lactation:

Do not use during pregnancy or lactation.

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.

Overdose:

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.

Special restrictions for use and special conditions for use:

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## 7. Adverse events

Dogs:

<i>Rare (1 to 10 animals / 10 000 animals treated):</i>
Diarrhoea <sup>1</sup> , loose stool, emesis (vomiting) Lethargy
<i>Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports):</i>
Tachycardia <sup>2</sup> (increased heart rate), high blood pressure <sup>2</sup> , arrhythmia (irregular heartbeat) Proteinuria <sup>3</sup> (presence of protein in the urine) Wobbliness, ataxia (difficulty coordinating movements), seizure Decreased appetite Collapse, polydipsia (increased thirst) Aggression, hyperactivity (agitation) Hypersensitivity Polyuria (increased urination)

<sup>1</sup> Liquid

<sup>2</sup> Effects of sympathomimetics producing excessive stimulation of the sympathetic nervous system

<sup>3</sup> Due to increased blood pressure.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: To be completed nationally.

## 8. Dosage for each species, routes and method of administration

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 1mg/kg bodyweight 3 times daily in the feed, corresponding to 0.1 ml of the veterinary medicinal / 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.

## 9. Advice on correct administration

None.

## 10. Withdrawal periods

Not applicable.

## 11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label or on the carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 months.

## **12. Special precautions for disposal**

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

To be completed nationally.

### **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.

## **15. Date on which the package leaflet was last revised**

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

## **16. Contact details**

Marketing authorisation holder <,> <and> <manufacturer responsible for batch release> <and contact details to report suspected adverse events>:

To be completed nationally.

Manufacturer responsible for batch release:

Vetoquinol S.A.  
Magny-Vernois  
70200 Lure  
France

Local representatives and contact details to report suspected adverse events:

To be completed nationally.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

## **17. Other information**

### Pharmacodynamics:

The clinical effect of phenylpropanolamine in urinary incontinence is based on its stimulation effect on  $\alpha$ -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

### 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