ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box - 30 ml (and 100 ml) bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROPALIN, 40.28 mg/ml, syrup for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Phenylpropanolamine hydrochloride .....50.00 mg
(Equivalent to 40.28 mg phenylpropanolamine)

3. PACKAGE SIZE

30 ml.
100 ml.
1 oral syringe

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 3 months.

Use by…

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol SA

14. MARKETING AUTHORISATION NUMBERS

Vm 06462/3010

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL – 100 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROPALIN , 40.28 mg/ml, syrup

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Phenylpropanolamine hydrochloride .....50.00 mg
(Equivalent to 40.28 mg phenylpropanolamine)

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, used within 3 months.

Use by…

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol SA

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL – 30 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROPALIN

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
Phenylpropanolamine hydrochloride .....50.00 mg
(Equivalent to 40.28 mg phenylpropanolamine)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 3 months.
Use by…

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

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:

Rare (1 to 10 animals / 10 000 animals treated):
Diarrhoea[1], Loose stool, Emesis (vomiting) Lethargy
Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Tachycardia[2] (increased heart rate), High blood pressure[2], Arrhythmia (irregular heartbeat), Proteinuria[3] (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)

[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 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:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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 1 mg of phenylpropanolamine hydrochloride for 1 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

Vm 06462/3010

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Vetoquinol S.A.
34 Rue de Chene Sainte-Anne
Magny-Vernois
70200 Lure
France

Local representatives and contact details to report suspected adverse events:

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS
Tel: +44 (0)1280 814 500

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 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

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

POM-V

Gavin Hall

Approved: 04 August 2026