LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON **- 100 ml bottle and 30 ml bottle**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROPALIN Syrup, 40 mg/ml, dogs
Phenylpropanolamine

2. STATEMENT OF ACTIVE SUBSTANCES

Phenylpropanolamine (as hydrochloride)…….40.28 mg/ml

3. PHARMACEUTICAL FORM

Syrup

4. PACKAGE SIZE

30 ml
100 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral administration.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once opened, use within 3 months
Once opened, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

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

Disposal: read package leaflet

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

For animal treatment only
To be supplied only on veterinary prescription.

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

To be completed nationally.

16. MARKETING AUTHORISATION NUMBER

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL – 100 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROPALIN Syrup, 40 mg/ml, dogs
Phenylpropanolamine

2. STATEMENT OF ACTIVE SUBSTANCES

Phenylpropanolamine (as hydrochloride)…….40.28 mg/ml

3. PHARMACEUTICAL FORM

Syrup

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral administration.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once opened, used within 3 months.
Once opened, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep the bottle in the outer carton in order to protect from light.

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

Disposal: read package leaflet.

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

For animal treatment only
To be supplied only on veterinary prescription.

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

To be completed nationally.

16. MARKETING AUTHORISATION NUMBER

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL – 30 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROPALIN Syrup, 40 mg/ml, dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Phenylpropanolamine (as hydrochloride)…….40.28 mg/ml

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

30 ml

4. ROUTE(S) OF ADMINISTRATION

Oral administration.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP:
Once opened, use within 3 months
Once opened, use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
PROPALIN Syup, 40 mg/ml, dogs

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

Marketing authorisation holder:
To be completed nationally.

Manufacturer responsible for batch release:
VETOQUINOL S.A.
Magny-Vernois
F-70200 Lure
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROPALIN Syrup, 40 mg/ml, dogs
Phenylpropanolamine

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:
Phenylpropanolamine 40.28 mg
(Equivalent to 50 mg phenylpropanolamine hydrochloride)

Excipients, q.s.

Colourless to slightly yellow-brown solution.

4. INDICATION(S)

Treatment of urinary incontinence associated with urethral sphincter incompetence in the bitch.
Efficacy has only been demonstrated in ovariohysterectomised bitches.

5. CONTRAINDICATIONS

The use of Propalin is not appropriate for the treatment of behavioural causes of inappropriate urination. Do not administer to patients treated with non-selective monoamine oxidase inhibitors.
Do not use in case of known hypersensitivity to active substance or to any of the excipients.

6. ADVERSE REACTIONS

Sympathomimetics may produce very rarely a wide range of effects, most of which mimic the results of excessive stimulation of the sympathetic nervous system such as effects on heart rate (tachycardia (increased heart rate)) or effects on blood pressure (increased blood pressure), which can induce proteinuria.

Dizziness, decrease in appetite, arrythmia, collapse, aggression, hyperactivity (including restlessness), polydipsia (increased drinking), polyuria (increased urination), ataxia (incoordination), seizure and hypersensitivity may occur in very rare cases.
Liquid diarrhoea/loose stool, emesis (vomiting) and lethargy have been reported rarely.

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.

Alternatively you can report via your national reporting system *{national system details}*.

7. TARGET SPECIES

Dogs.

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

The recommended dose for Propalin is 1mg/kg bodyweight 3 times daily in the feed, corresponding to 0.1 ml Propalin Syrup / 5 kg bodyweight (i.e., a graduation of the provided syringe for 5 kg), 3 times daily.
The absorption rate is increased if the product is administered to fasted dogs.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

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 after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 3 months

12. SPECIAL WARNING(S)

Special precautions for use in animals:

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 product must be used and kept out of reach of children. Always replace the cap securely after use.

In the event of accidental ingestion, seek immediate medical attention showing the physician the package insert.

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 Propalin Syrup with other sympathomimetic drugs, anticholinergic drugs, tricyclic antidepressants or specific type B monoamine oxidase inhibitors. It should not be used in patients treated with non-selective monoamine oxidase inhibitors.

Overdose (symptoms, emergency procedures, 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.

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

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon or pharmacist 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

For animal treatment only.

Pharmacodynamic properties
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

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

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.