SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROPALIN Syrup, 40 mg/ml, dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of product contains
Phenylpropanolamine (as hydrochloride)..... 40.28 mg
Excipient..... to 1 ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.
Colourless to slightly yellow-brown solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 secure 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.

4.6 Adverse reactions (frequency and seriousness)

In the course of field clinical trials, loose stools, liquid diarrhoea, decrease in appetite, arrhythmia and collapse were reported in some dogs. Treatment was continued depending on the severity of the undesirable effect observed.
Sympathomimetics may produce a wide range of effects, most of which mimic the results of excessive stimulation of the sympathetic nervous system (e.g. effects on heart rate and blood pressure).
Dizziness and restlessness were also occasionally reported. Hypersensitivity may occur in very rare cases

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant or lactating bitches.

4.8 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.

4.9 Amounts to be administered and administration route

Oral use.

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 3 times daily.
The absorption rate is increased if the product is administered to fasted dogs.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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 sympathic 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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Phenylpropanolamine hydrochloride is a sympathomimetic agent. It is an analogue of the endogenous sympathomimetic amines.
ATCVet code: QG04BX91

5.1 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.

5.2 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol solution (70% w/v) non crystallising.

6.2 Major incompatibilities

None known.

6.3 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

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate.

6.5 Nature and composition of immediate packaging

30 ml and 100 ml: 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.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused products or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

8. MARKETING AUTHORISATION NUMBER

Vm 08007/4035

9. DATE OF FIRST AUTHORISATION

27 January 1993

10. DATE OF REVISION OF THE TEXT

12 November 2019

Approved 12 November 2019