1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROPALIN Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance
Phenylpropanolamine Hydrochloride 50mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.
A clear syrup. The colour of the product may change from clear to yellow/brown over time. This does not adversely affect the quality of the product.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Phenylpropanolamine is a sympathomimetic agent which acts by direct stimulation of the smooth muscle of the internal urethral sphincter. It is indicated in the management of urinary incontinence associated with urethral sphincter incompetence in the bitch, particularly that associated with ovariohysterectomy.

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

Propalin syrup should be avoided in hypertensive individuals.

4.5 Special precautions for use

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 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)

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) or effects on blood pressure (increased blood pressure), which can induce proteinuria.
Dizziness, decrease in appetite, arrhythmia, collapse, aggression, hyperactivity (including restlessness), polydipsia, polyuria, ataxia, seizure and hypersensitivity may occur in very rare cases.
Liquid diarrhoea/loose stool, emesis and lethargy have been reported rarely.

The vehicle sorbitol syrup has laxative properties but such activity is unlikely at the recommended dosage.

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).

4.7 Use during pregnancy, lactation or lay

Propalin Syrup should not be administered to pregnant animals. There are no literature reports of systemic effects of phenylpropanolamine on reproduction and fertility and no associated clinical studies in humans.

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

For oral administration.
The recommended dose of phenylpropanolamine is 1.5 mg/kg bodyweight twice daily. This dosage may be measured in an oral syringe at a rate of 0.15 ml per 5 kg bodyweight twice daily in the feed. Alternatively, 1 mg/kg bodyweight 3 times daily may be given and can be measured in an oral syringe at a rate of 0.1 ml per 5 kg bodyweight 3 times daily in the feed.

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

Lethargy and inappetence have been reported in a dog following an overdose of 2.5 mg/kg 3 times daily.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Genito urinary system ans sex hormones, phenylpropanolamin.
ATCvet Code: QG04BX91

5.1 Pharmacodynamic properties

Phenypropanolamine hydrochloride is a sympathomimetic agent. It is an analogue of the endogenous sympathomimetic amines. Phenylpropanolamine hydrochloride has weak sympathomimetic activity and produces a wide range of pharmacological effects. It appears to act directly on the smooth muscle of the lower urinary tract. The smooth muscle is thought to be largely responsible for the maintenance of tone in the resting state.

5.2 Pharmacokinetic particulars

The pharmacokinetic properties of Phenylpropanolamine hydrochloride have not been studied in the dog. In man, the mean half-life of Phenylpropanolamine is about 5 hours with maximal plasma concentrations being found after about 2.5 hours. Phenylpropanolamine is eliminated in the urine with no appreciable metabolism, the elimination half-life being about 3 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol solution (70% w/v)

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

6.4. Special precautions for storage

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

6.5 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.

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 Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

VPA10983/056/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14 July 1993

10 DATE OF REVISION OF THE TEXT

22 January 2024