Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Propalin Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance
Phenylpropanolamine Hydrochloride 50 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution. A clear colourless syrup

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
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 a wide range of effects, most of which mimic the results of excessive stimulation of the sympathetic nervous system. Headaches, hypertension and dizziness have been reported in man.
Aggressiveness and restlessness have been noted in some dogs following treatment.
The vehicle sorbitol syrup has laxative properties but such activity is unlikely at the recommended dosage.

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 interactions

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 %)

6.2 Major incompatibilities

None known.

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. Store in a dry place. Do not refrigerate.

6.5 Nature and composition of immediate packaging

Propalin syrup is available in two pack sizes:

30ml pack: HDPE bottle with LDPE syringe adaptor insert and a polypropylene child resistant closure. The package also contains one LDPE/polystyrene 1.5 ml graduated syringe.
100 ml white high density polyethylene bottles fitted with a low density white polyethylene syringe adaptor insert a white high density polypropylene wadded click-lock child resistant closure. The package contains one 1.5 ml graduated syringe of LDPE/ polystyrene.

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

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

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
12 Northbrook Road
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Dublin 6
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/056/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 July 1993
Date of last renewal: 13 July 2008

10 DATE OF REVISION OF THE TEXT

August 2019