# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Proin 50 mg chewable tablets for dogs

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

**Active substance:**

| | | |
|---|---|---|
| Phenylpropanolamine Hydrochloride | 50 | mg |
| (as phenylpropanolamine) | 40.3 | mg |

**Excipients:**
Dark Brown lake LB506

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Chewable tablet.

Liver-flavoured, brown coloured, round, biconvex, un-coated tablets, with a break-line on one side and embossed with PROIN 50 on the other side.
The tablets can be divided into halves.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Dogs.

### 4.2 Indications for use, specifying the target species

For the management of urinary incontinence associated with urethral sphincter incompetence in the bitch, particularly that associated with ovariohysterectomy.

### 4.3 Contraindications

Do not use in hypertensive animals or in animals that become hypertensive after initiating therapy.
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

In bitches less than 1 year old the possibility of anatomical disorders contributing to incontinence should be considered prior to treatment.
Do not use the product for the treatment of behavioural causes of inappropriate urination.

### 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.

Phenylpropanolamine has been shown to increase mean arterial blood pressure resulting in hypertension over time. Animals administered the product should therefore be monitored for signs of hypertension, particularly with prolonged use of the product. Care should be exercised in treating animals with pre-existing heart disease, renal or hepatic insufficiency, diabetes mellitus, hyperadrenocorticism, glaucoma, hyperthyroidism or other metabolic disorders that may predispose to hypertension.

Instances of dogs chewing through closed bottles and eating the bottle contents have been reported. Store the product securely out of reach of dogs and other pets in order to prevent access and possible overdose. In case of overdose, consult a veterinarian (See section 4.10).

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.

People with known hypersensitivity to phenylpropanolamine or any of the excipients should avoid contact with the veterinary medicinal product.

To avoid accidental ingestion, the product must be used out of sight of children and stored out of sight and reach of children. Always replace unused tablets back into container and 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.

This product can cause skin-irritation. Avoid prolonged exposure to product. Wash hands after use.

This product can cause eye-irritation. In the event of accidental eye contact, rinse immediately with plenty of water and seek medical attention if irritation occurs.

**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 (e.g. hypertension).

Vomiting/emesis and anorexia have been very commonly reported and diarrhoea, lethargy, agitation and panting commonly reported.

If adverse reactions occur, depending on the severity of the signs observed, treatment should be discontinued and the advice of a veterinarian should be sought.

Aggressiveness and restlessness have been noted in some dogs following treatment.

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**

Do not administer to pregnant or lactating animals. There are no reports of systemic effects of phenylpropanolamine on reproduction and fertility.

**4.8 Interaction with other medicinal products and other forms of interactions**

Care should be exercised in administering the product 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 of phenylpropanolamine hydrochloride is 1.5 mg/kg bodyweight twice daily.
The product should be administered at the time of feeding or shortly after.

The following table can be used as a guide to administer the recommended dose:

| Number of tablets to be administered twice daily | bodyweight range (kg) |
|---|---|
| 1 tablet | >25-33 |
| 1.5 tablets | >33-50 |
| 2 tablets | >50-65 |

The remaining tablet portion should be given at the next administration.

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

Vomiting/emesis, diarrhoea, anorexia, agitation, arrhythmia, erythema, fever, hypersalivation, hypertension, lethargy, mydriasis, panting, piloerection, tachycardia, tremor, and urinary retention may be observed when a dose higher than the recommended dosage is administered.

In a target animal safety study investigating tolerance to administration of 2, 6 and 10 mg phenylpropanolamine hydrochloride/kg bodyweight twice daily, mean arterial blood pressure was observed to increase in a dose-dependent and time dependant manner over the 26 week duration of the study resulting in hypertension being observed at all three dose rates.

Treatment should be symptomatic. Alpha-adrenergic blockers may be appropriate in the case of severe overdose.

**4.11 Withdrawal period(s)**

Not applicable.

**5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Genito urinary system and sex hormones, urologicals, phenylpropanolamine.
ATCvet code: QG04BX91.

**5.1 Pharmacodynamic properties**

Phenylpropanolamine is a racemic mixture of D and L enantiomers.
Phenypropanolamine hydrochloride is a sympathomimetic agent which acts by direct stimulation of the smooth muscle of the internal urethral sphincter. 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**

Phenylpropanolamine is rapidly absorbed. Following oral administration shortly after feeding at the recommended dose of 1.5 mg/kg phenylpropanolamine, maximal phenylpropanolamine plasma concentrations are reached in less than 2 hours and the elimination half-life is between 3 and 4 hours.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Calcium hydrogen phosphate dihydrate
Silica colloidal anhydrous
Sorbitol
Stearic acid
Whey
Powdered soy protein concentrate
Chicken liver powder
Dry liver flavour
Dry garlic flavour
Garlic powder
Brewer's yeast
Dark Brown Lake LB506

### 6.2 Major incompatibilities

Not applicable.

### 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 30°C.

### 6.5 Nature and composition of immediate packaging

White high density polyethylene bottles containing a 5 gram desiccant pack and cotton, sealed with a child resistant, foil lined heat sealed white polypropylene cap.

Pack size: 60 tablets.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## 7 MARKETING AUTHORISATION HOLDER

Pegasus Laboratories Ireland Limited
10 McCurtain Hill
Clonakilty
County Cork
Cork
P85 K230
Ireland

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA22713/001/002

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 March 2018

## 10 DATE OF REVISION OF THE TEXT

April 2019