LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

BOTTLE LABEL

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

Marketing authorisation holder:
Pegasus Laboratories UK Limited
Bridge House
2 Bridge Avenue
Maidenhead
Berkshire
SL6 1RR
United Kingdom

Manufacturer responsible for batch release:
Tairgi Tread-Lia Baile na Sceilge Teo T/A Ballingskelligs Veterinary Products
Ballinskelligs
Co. Kerry
V23 XR52
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROIN 50 mg chewable tablets for dogs
Phenylpropanolamine hydrochloride

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

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.

Each tablet contains
Phenylpropanolamine Hydrochloride 50 mg
(as phenylpropanolamine) 40.3 mg
Colourant: Dark Brown lake LB506

4. PHARMACEUTICAL FORM

Chewable tablet

5. PACKAGE SIZE

60 tablets

6. INDICATION(S)

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

7. 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.

8. ADVERSE REACTIONS

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).

If you notice any serious effects or other effects not mentioned in this label, please inform your veterinary surgeon.

9. TARGET SPECIES

Dogs

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

Oral use.

The recommended dose of phenylpropanolamine hydrochloride is 1.5 mg/kg bodyweight twice daily.

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 tablet	>33-50
2 tablets	>50-65

11. ADVICE ON CORRECT ADMINISTRATION

The product should be administered at the time of feeding or shortly after.
The remaining tablet portion should be given at the next administration.

12. WITHDRAWAL PERIOD(S)

Not applicable.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the bottle.
The expiry date refers to the last day of that month.

14. SPECIAL WARNING(S)

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.

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.

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.

Pregnancy and lactation

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

Interaction with other medicinal products and other forms of interaction

Care should be exercised in administering the product with other sympathomimetic drugs, anticholinergic drugs, tricyclic antidepressants or specific type B monoamine oxidase inhibitors.

Overdose (symptoms, emergency procedures, antidotes):

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.

Incompatibilities:

None known.

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

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

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

February 2021

17. OTHER INFORMATION

Distributor:
Forte Healthcare Ltd
Unit 9, Block 3
CityNorth Business Campus, CityNorth
Stamullen, Co. Meath
Republic of Ireland

18. 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.

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

20. EXPIRY DATE

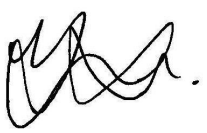
EXP {month/year}

21. MARKETING AUTHORISATION NUMBER(S)

Vm 52615/4001

22. MANUFACTURER'S BATCH NUMBER

Lot {number}



Approved: 05 August 2022