Vetoquinol UK Ltd

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Propalin™ Syrup, 40mg/ml for Dogs

Species: Dogs

Therapeutic indication:Pharmaceuticals: Neurological preparations: Others

Active ingredient: Phenylpropanolamine Hydrochloride

Product: Propalin™ Syrup, 40mg/ml for Dogs

Product index: Propalin Syrup

Incorporating:

Presentation

Each ml contains:

Active substance:

Phenylpropanolamine 40.28 mg

(Equivalent to 50 mg phenylpropanolamine hydrochloride)

Syrup. Colourless to slightly yellow-brown solution.

Uses

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

Dosage and administration

Oral use.

The recommended dose is 0.8mg phenylpropanolamine/kg bodyweight (equivalent to 1mg/kg phenylpropanolamine hydrochloride/kg) 3 times daily in the feed, corresponding to 0.1 ml Propalin Syrup/5 kg bodyweight (i.e., a graduation of the provided syringe for 5 kg), 3 times daily.

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

Contra-indications, warnings, etc

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.

Adverse reactions (frequency & 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 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 treated)

- uncommon (more than 1 but less than 10 animals in 1,000 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).

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.

Use during pregnancy, lactation or lay

Do not administer to pregnant or lactating bitches.

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. It should not be used in patients treated with non-selective monoamine oxidase inhibitors.

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 sympathetic 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.

Major incompatibilities

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

Withdrawal periods

Not applicable

Operator warning

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 securely 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.

Pharmaceutical precautions

Do not store above 25°C.

Keep the bottle in the outer carton in order to protect from light.

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

Shelf life after first opening the immediate packaging: 3 months.

When the container is opened for the first time, using the in-use shelf-life which is specified above (3 months), the date on which any product remaining in the container should be discarded, should be worked out. This discard date should be written in the space provided on the carton

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

Legal category

Legal category:POM-V

Packaging quantities

30ml and 100 ml: HDPE bottle with LDPE syringe adapter insert and a polypropylene child resistant closure; the package contains also one 1.5ml 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.

Further information

Pharmacological Immunological Properties

Phenylpropanolamine hydrochloride is a sympapathomimetic agent. It is an analogue of the endogenous sympathomimetic amines. ATC Vetcode: QG04BX91.

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.

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 1mg/phenylpropanolamine hydrochloride/kg 3 times daily over 15 days.

When the product is administered to a fasted dog, bioavailability is increased significantly.

Marketing Authorisation Number

NI: 06462/3010

GB: 08007/5019

NOAH Compendium

Significant changes

GTIN

GTIN description: Propalin Syrup 30ml

GTIN:03605870009794

GTIN description: Propalin Syrup 100ml

GTIN:03605870009800