Package leaflet for a veterinary preparation

The medicine is dispensed by a veterinarian's prescription only

For animal use only

1. Name, form and strength of the veterinary medicine

Propalin Vetrinary, syrup, 5% W/V

2. Active ingredients and quantity in a single dose:

Phenylpropanolamine hydrochloride 5% W/V.

Each 1 mL syrup of Propalin Vetrinary contains:
40.28 mg phenylpropanolamine (equivalent to 50 mg phenylpropanolamine hydrochloride)

For the list of excipients in the preparation, please see Section 13.

3. What is the medicine intended for

Treatment of urinary incontinence associated with urethral sphincter incompetence in the bitch.

Therapeutic group: sympathomimetic drug acting on the central nervous system: an alpha-adrenergic receptor agonist.

4. Contraindications

Not to be used in cases with known hypersensitivity to the active substance or to any of the other ingredients in the preparation.

Efficacy of the preparation has only been demonstrated in ovariohysterectomized bitches.
The use of Propalin is not appropriate for the treatment of behavioral causes of inappropriate urination.
Do not administer to bitches treated with non-selective monoamine oxidase inhibitors.

5. Side effects

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 (increased heart rate)] or effects on blood pressure (increased blood pressure), which can induce loss of protein in the urine (proteinuria).

Dizziness, decrease in appetite, heart rate disturbance (arrhythmia), collapse, aggression, hyperactivity (including restlessness), excessive thirst that causes drinking too much (polydipsia), increased urination (polyuria), impaired coordination of voluntary movements (ataxia), seizures and hypersensitivity can occur in very rare cases.

Liquid diarrhea/loose stool, vomiting and lethargy (a decrease in consciousness or fatigue without feeling the need to sleep) have been reported rarely.

The frequency of side effects is defined by the following criteria:

- Very common side effects (occurring in more than 1 of 10 animals treated)
- Common side effects (occurring in more than 1 of 10, but in less than 10 of 100 animals treated)
- Uncommon side effects (occurring in more than 1, but in less than 10 of 1000 animals treated)
- Rare side effects (occurring in more than 1, but in less than 10 of 10000 animals treated)
- Very rare side effects (occurring in less than 1 of 10000 animals treated, including isolated reports)

If you notice any side effects, even those not listed in the in this leaflet, or if you think that the medicine does not work, please refer to the doctor or report to the Ministry of Health.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects due to medical treatment," located in the Ministry of Health homepage: (www.health.gov.il), which directs to an online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

6. Target animals: Bitches

7. Dosage and administration

The usual dose is 1 mg per 1 kg body weight 3 times daily, in the feed.

This is equivalent to 0.1 ml Propalin per each 5 kg body weight, three times daily.

For example: 0.5 ml for a female dog weighing 25 kg, three times a day.

The absorption rate of the drug is increased in fasting female dogs.

8. Instructions for use of the preparation

Propalin syrup should be applied directly to the animal's feed.

9. Withdrawal period

Not applicable

10. Warnings

- Special warnings regarding the use of the medicine in the target animal

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; therefore, caution should be exercised when administered to 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, 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 (the active substance in the medicinal product) is toxic when taking an overdose. Possible side effects: dizziness, headache, nausea, insomnia or restlessness, and increased blood pressure. High overdosing may be fatal, especially in children.
- To avoid inadvertent swallowing, the product must be used and kept out of reach of children. Always close after use with the dedicated cap, which is difficult for children to open.
- In the event of accidental swallowing, please seek immediate medical help and show the package insert to the physician.
- In the event of accidental skin contact, wash thoroughly the contaminated area with water and soap.
- Wash hands after using the preparation.
- In the event of accidental eyes contact, rinse the eyes with clean water for 15 minutes and consult a physician.

- Pregnancy and lactation of the treated animal

Do not administer to pregnant or lactating bitches.

- Interactions with other medicines and other forms of interaction

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

  The medicine must not be used in patients treated with non-selective monoamine oxidase inhibitors.

- Overdose

  In healthy dogs, no side effects were observed at up to 5 times the recommended dosage. However, an overdose of phenylpropanolamine (the active ingredient) 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.

11. Storage instructions

- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach and sight of children and/or infants to prevent accidental poisoning.
- The medicine must not be used after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of the month shown.
- Storage conditions: Do not store above 25°C. The bottle must be kept in its original carton to protect it from light. After the first opening, may be used for 90 days.

12. Instructions for the disposal of the preparation/preparation residues after use

Any unused veterinary medical product or any substance remaining after using the veterinary medical product must be disposed of as toxic waste; do not throw into the sewage system.

13. Additional information

- Besides the active substance, the medication also includes:
  Sorbitol solution (70% w/v) non-crystallizing
- How the medicine looks and contents of the package – plastic bottles of 30 or 100 ml volume with a syringe adapter nozzle and a child resistant cap. The package also contains one 1.5 ml syringe with markings.

  Not all pack sizes may be marketed.

- Manufacturer: Vetoquinol S.A. Magny-vernois, 70200 Lure, France
- License holder: Eliezer Linevitz Ltd., 6, Edom St., P.O.B. 7006, Kanot Industrial Zone, Gedera 7982501

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Registration number of the medicine in the National Drug Registry of the Ministry of Health 083-21-92354