

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENURACE 50, 50 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

40.7 mg ephedrine equivalent to 50 mg ephedrine hydrochloride.

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

Round, white tablet with break line on one side and inscription ENURACE 50 on the other side.

4. CLINICAL PARTICULARS

4.1 Target species

Dog (ovariohysterectomised female dogs).

4.2 Indications for use, specifying the target species

Treatment of urinary incontinence caused by urethral sphincter mechanism incompetence in ovariohysterectomised female dogs.

4.3 Contraindications

Do not use in dogs with glaucoma.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

This product is not suitable for treatment of inappropriate urination due to behaviour problems.

4.5 Special precautions for use

Special precautions for use in animals

Do not use the product in dogs under 20 kilogram of bodyweight.

As ephedrine is an alpha- and beta-adrenergic receptor agonist, the product should be used with caution in dogs with cardiovascular disease and only after a comprehensive risk/benefit analysis by the attending veterinarian.

The dog's cardiovascular functionality should be carefully assessed before the start of the treatment with the product and it should be periodically monitored during the treatment.

In addition, a similar approach should be adopted in animals suffering from partial urethral obstruction, hypertension, diabetes mellitus, hyperadrenocorticism, hyperthyroidism or other metabolic disorders. It should be mentioned that the polyuria/polydipsia (PU/PD) frequently accompanying the aforementioned conditions may be falsely diagnosed as urinary incontinence.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Ephedrine hydrochloride could be toxic if ingested. Adverse effects may include insomnia and nervousness, dizziness, headache, increased blood pressure, increased sweating and nausea.

Ingestion may be fatal, especially in children. To avoid accidental ingestion, the product must be used and kept out of the reach of children. Always replace the cap securely after use.

In case of accidental ingestion, most importantly by children, seek medical advice immediately and show the package leaflet or the label to the physician.

It is strongly recommended that pregnant women should wear gloves for administration.

Wash hands after administration.

4.6 Adverse reactions (frequency and seriousness)

- Cardiovascular effects like tachycardia, atrial fibrillation, stimulation of the heart activity; and vasoconstriction.
- Stimulation of the central nervous system leading to sleeplessness, excitation, anxiety and muscle tremors.
- Panting.
- Mydriasis.
- Cystitis.
- Bronchodilatation and decrease of mucus release in the respiratory mucosal membranes.
- Reduction of the motility and tone of the intestinal wall.

Due to the nature of ephedrine the mentioned effects can occur at the recommended therapeutic dose, with anxiety and cardiovascular effects being the most prevalent. In 10% of the treatments, side effects have been observed in efficacy studies.

Vomiting has been reported very rarely in spontaneous reports.

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

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

- Ephedrine may interact with other sympathomimetics.
- Ephedrine may enhance glucocorticoid metabolism.
- Concomitant use with MAO-inhibitors may cause hypertension.
- Ephedrine can enhance the activity of products of the same class as theophylline.
- Volatile anaesthetics may enhance the sensitivity of the myocardium to the cardiovascular effects of ephedrine.
- Concomitant use with cardiac glycosides, quinine and tricyclic antidepressants can cause arrhythmias.
- Vascular constrictions can occur after concomitant treatment with ergot alkaloids and oxytocin.
- Substances leading to an increase in pH of the urine are able to prolong the excretion of ephedrine, whereas substances leading to a decrease in pH of the urine are able to accelerate the excretion of ephedrine.

4.9 Amounts to be administered and administration route

For oral administration only.

A starting dose of 2 mg ephedrine HCl per kg of bodyweight per day, divided in two oral doses is recommended. Dogs can be dosed according to the following table:

Weight (kg)	Dose (mg/day)	Dose (Number of tablets)		
		per day	1 st gift	2 nd gift
20-30	50	1	½	½
31-40	75	1 ½	½	1
41-50	100	2	1	1

Desired therapeutic effect and occurrence of adverse effects have to be monitored approximately at

14 days, 1 month, 3 months and 6 months after the start. Based on the observed effect in comparison with the expected effect and taking into account the occurrence

of adverse effects, the individual dose should be adjusted. The dose should be adjusted to find the lowest effective dose. Once the effective dose has been established, dogs should still be monitored at regular intervals, e.g. every six months.

The product should be administered before meals in a piece of food.

A maximum dose of 5 mg/ kg of bodyweight per day has to be respected.

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

The signs of overdose resemble those of the adverse reactions as described in section 4.6. In case of overdose, it is useful to accelerate excretion of ephedrine by acidification of the urine and enhanced diuresis.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: urologicals.
ATC vet code: QG04BX90.

5.1 Pharmacodynamic properties

Ephedrine directly stimulates alpha- and beta-adrenergic receptors, present in all organ systems. It also stimulates the release of catecholamines from sympathetic neurons. Since ephedrine passes the blood-brain barrier, it also induces effects that are mediated through the central nervous system.

Ephedrine specifically causes a contraction of the internal urethral sphincter muscles and a relaxation of the bladder muscles through a sympathomimetic action on the adrenergic receptors.

5.2 Pharmacokinetic particulars

Ephedrine is rapidly absorbed, and the bioavailability is high. Ephedrine is widely distributed over the body. Degradation by demethylation to norephedrine is the major metabolic pathway. Within 48 hours, urinary excretion accounts for elimination of 80 to 90 % of the administered dose, at high urinary acidity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal silica
Lactose monohydrate
Microcrystalline cellulose
Magnesium stearate

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original container.

Divided tablets should be returned in the original package and used in the subsequent dose. Close the cap to the click.

6.5 Nature and composition of immediate packaging

White polypropylene container containing 100 tablets, with child-resistant closure system, in a cardboard box. The packaging might also contain a polyurethane cover-up.

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

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

7. MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020, Oostkamp
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 32742/4002

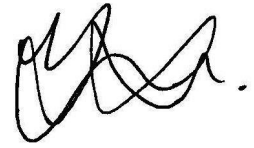
9. DATE OF FIRST AUTHORISATION

04 January 2008

10. DATE OF REVISION OF THE TEXT

November 2020

PROHIBITION OF SALE, SUPPLY AND/OR USE
To be supplied only on veterinary prescription.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 10 November 2020