SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENURACE 10, 10 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:
Ephedrine 8.1 mg
(equivalent to 10 mg ephedrine hydrochloride)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Ponceau 4R (E124)	0.08 mg
Colloidal silica	
Lactose monohydrate	
Maize starch	
Magnesium stearate	

Round, pink tablet with a break line on one side and the inscription ENURACE 10 on the other side.

3. CLINICAL INFORMATION

3.1 Target species

Dog (bitch).

3.2 Indications for use for each target species

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

3.3 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.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

The safety and the efficacy of the veterinary medicinal product has not been assessed in dogs under 5 kg. Do not use the veterinary medicinal product in dogs under 5 kilograms of bodyweight.

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

The dog's cardiovascular functionality should be carefully assessed before the start of the treatment with the veterinary medicinal 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 veterinary medicinal 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 during administration.

Wash hands after administration.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dog (bitch):

Undetermined frequency (cannot be estimated from the available data):	Cardiovascular system disorder (e.g. Tachycardia, Atrial fibrillation, Stimulation of heart activity, Peripheral vasoconstriction); Not sleeping; Excitation, Anxiety; Muscle tremor, Mydriasis; Cystitis; Respiratory tract disorder[1], Panting; Digestive tract hypomotility.

[1] Bronchodilatation and decrease of mucus release in the respiratory mucosal membranes.

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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 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.

3.9 Administration routes and dosage

Oral use.

A starting dose of 2 mg ephedrine hydrochloride 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	1st gift	2nd gift
5	10	1	½	½
7,5	15	1 ½	½	1
10	20	2	1	1
12,5	25	2 ½	1	1 ½
15	30	3	1 ½	1 ½
17,5	35	3 ½	1 ½	2
For weights superior or equal to 20 kg, use a higher strength of the product.				

The desired therapeutic effect and occurrence of adverse events 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 events, 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 veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The signs of overdose resemble those of the adverse events as described in section3.6. In case of overdose, it is useful to accelerate excretion of ephedrine by acidification of the urine and enhanced diuresis.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QG04BX90

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25°C.
Store in the original container.
Divided tablets should be returned in the original container and used in the subsequent dose. Close the cap to the click.

5.4 Nature and composition of immediate packaging

White polypropylene container containing 60 tablets, with child-resistant closure system, in a cardboard box. The packaging might also contain a polyurethane cover-up.

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

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with

any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV

7. MARKETING AUTHORISATION NUMBER

Vm 32742/4001

8. DATE OF FIRST AUTHORISATION

30 March 2010

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

October 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 03 November 2026