PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENURACE 10, 10 mg tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Per tablet 10 mg ephedrine hydrochloride.

3. PACKAGE SIZE

60 tablets.

4. TARGET SPECIES

Dog (bitch)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV

14. MARKETING AUTHORISATION NUMBERS

Vm 32742/4001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {POLYPROPYLENE CONTAINER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENURACE 10, 10 mg tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Per tablet 10 mg ephedrine hydrochloride.

3. TARGET SPECIES

Dog (bitch)

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

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.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ENURACE 10, 10 mg tablets for dogs

2. Composition

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

Excipients:
Ponceau 4R (E124): 0.08 mg

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

3. Target species

Dog (bitch).

4. Indications for use

Treatment of unwanted loss of urine (urinary incontinence) due to low tension in the circular muscles closing the urethra (urethral sphincter mechanism incompetence) in ovariohysterectomised female dogs.

5. Contraindications

Do not use in dogs with increased pressure in the eye (glaucoma).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

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

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 kg 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:
It is strongly recommended that pregnant women should wear gloves during administration.
Wash hands after administration.

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

Interaction with other medicinal products and other forms of interaction:
Ephedrine may interact with other sympathomimetics.
Ephedrine may enhance the metabolism of hormones of the pituitary gland (glucocorticoid metabolism).
Concomitant use with MAO-inhibitors (used for treatment of depression) may cause increased blood pressure (hypertension).
Ephedrine can enhance the activity of products of the same class as theophylline (used in treatment of epilepsy).
Volatile anaesthetics may enhance the sensitivity of the heart muscle (myocardium) to the effects on heart and blood vessels (cardiovascular effects) of ephedrine.
Concomitant use with cardiac glycosides (used to increase the pump force of the heart), quinine (anti-infection) and tricyclic antidepressants (used for treatment of depressions) can cause disorders of the heart rhythm (arrhythmias).
Constrictions of the blood vessels (vascular constrictions) can occur after concomitant treatment with ergot alkaloids and oxytocin (both used for the induction of labour).
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.

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

7. Adverse events

Dog (bitch)

Undetermined frequency (cannot be estimated from the available data):	Cardiovascular system disorder (e.g. Tachycardia (rapid heart rate), Atrial fibrillation (irregular heartbeat), Stimulation of heart activity, Peripheral vasoconstriction (narrowing of blood vessels)); Not sleeping; Excitation, Anxiety; Muscle tremor (trembling of the muscles), Mydriasis (dilatation of the pupils); Cystitis (bladder infection); Respiratory tract disorder[1], Panting; Digestive tract hypomotility (slowing of intestinal movement).

[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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use.
Give 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.				

9. Advice on correct administration

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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.
Store in the original container.
Return divided tablet in the original container and use this tablet in the subsequent dose. Close the cap to the click.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after “EXP”. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 32742/4001

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

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium
Tel: + 32 50314269
info@ecuphar.be

Manufacturer responsible for batch release:
Pasteur Filiala Filipesti S.A
944 Principala Street
Filipestii de Padure, Prahova county
Romania

17. Other information

POM-V

Gavin Hall
Approved: 03 November 2026