

PARTICULARS TO APPEAR ON THE OUTER PACKAGE Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Caniphedrin 50 mg tablets

Ephedrine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Ephedrine hydrochloride 50 mg
(equivalent to 41.0 mg Ephedrine)

3. PACKAGE SIZE

100 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the blisters in the outer carton in order to protect from light. Do not refrigerate or freeze.

Unused divided tablets should be returned to the blister and used in the subsequent dose.

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

Accidental ingestion is dangerous. Pregnant women should wear impermeable gloves when handling the tablets.

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

VetViva Richter (logo)

14. MARKETING AUTHORISATION NUMBERS

Vm 57446/4020

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS – Blister with 10 tablets.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Caniphedrin



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Ephedrine hydrochloride 50 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

VetViva Richter (logo)

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Caniphedrin 50 mg tablets for dogs

2. Composition

Each tablet contains:

Active substance:

Ephedrine hydrochloride 50 mg
(equivalent to 41.0 mg Ephedrine)

White tablets with score line. The tablets can be divided into 2 equal parts.

3. Target species

Dogs

4. Indications for use

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

5. Contraindications

Do not use in dogs with cardiovascular disease (i.e. cardiomyopathy, tachycardic arrhythmia, hypertension), hyperthyroidism, diabetes mellitus, impaired renal function or glaucoma.

Do not use concurrently with halogenated narcotics such as halothane or methoxyflurane (see section 6).

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

6. Special warnings

Special warnings:

It is not appropriate to use the veterinary medicinal product for the behavioural cause of inappropriate urination.

In bitches less than 1 year old the possibility of anatomical disorders contributing to incontinence should be considered prior to treatment.

It is important to identify any underlying disease causing Polyuria/Polydipsia (PU/PD) which may be falsely diagnosed as urinary incontinence.

Special precautions for safe use in the target species:

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.

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

People with known hypersensitivity to ephedrine should avoid contact with the veterinary medicinal product.

Ephedrine hydrochloride could be toxic if ingested and ingestion may be fatal, especially to children. Adverse effects may include insomnia and nervousness, dizziness, headache, increased blood pressure, increased sweating and nausea. To avoid accidental ingestion, particularly by a child, the veterinary medicinal product must be administered out of the sight of children. Unused tablet parts should be returned to the open blister space and inserted back into the carton and kept in a safe place out of the sight and reach of children.

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 impermeable gloves when handling the tablets.

Wash hands thoroughly after administration of the veterinary medicinal product.

Pregnancy and lactation:

Not applicable.

Interaction with other medicinal products and other forms of interaction:

The potency of ephedrine and the risk of adverse reactions may be increased when administered together with methylxanthines and sympathomimetics.

Ephedrine may enhance glucocorticoid metabolism.

Concomitant use with MAO-inhibitors may cause hypertension.

Ephedrine may increase the risk for theophylline toxicity.

There is a risk of cardiac arrhythmias when combined with cardiac glycosides (e.g. digoxin), quinine, tricyclic antidepressants and halogenated narcotics (see section 5).

Substances leading to an increase in pH of the urine are able to prolong the excretion of ephedrine, which may lead to an increased risk of adverse reactions.

Substances leading to a decrease in pH of the urine are able to accelerate the excretion of ephedrine, which may lead to decreased efficacy.

Vascular constrictions can occur after concomitant treatment with ergot alkaloids and oxytocin.

Sympatholytics may decrease the efficacy of ephedrine.

Overdose:

At high overdoses, the following adverse events can occur: tachycardia, tachyarrhythmia, vomiting, increased transpiration, hyperventilation, muscle weakness, tremor with hyperexcitation and restlessness, anxiety and insomnia.

The following symptomatic treatment may be initiated:

- gastric lavage, if necessary
- in case of severe hyperexcitation, administration of sedatives such as diazepam or neuroleptics
- in case of tachyarrhythmia, administration of Beta-Blockers
- accelerated excretion by acidification of the urine and enhanced diuresis

<Special restrictions for use and special conditions for use:>
(to be completed in accordance with national requirements)

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):

Rapid pulse rate¹, Ventricular arrhythmia¹; Excitation¹.

Undetermined frequency (cannot be estimated from the available data):

Tachycardia², Atrial fibrillation², Increased heart rate², Peripheral vasoconstriction²; Not sleeping², Anxiety²; Muscle tremor², Mydriasis²; Pulmonary disorder (bronchodilatation and decrease of mucus release in the respiratory mucosal membranes)²; Digestive tract hypomotility².

¹These symptoms disappear following dose reduction or termination of treatment.

²Due to the pharmacological properties of ephedrine these effects can occur at the recommended therapeutic dose.

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:

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.

The tablets can be divided into 2 equal parts to ensure accurate dosing.

The recommended starting dose is 2 mg ephedrine hydrochloride (corresponding to 1.64 mg of ephedrine) per kg bodyweight (BW), equivalent to 1 tablet per 25 kg BW, per day during the first 10 days of treatment. The daily dose may be divided. Once the desired effect has been achieved, the dose can be reduced to one half or less. Based on the observed effect and taking into account the occurrence of adverse effects, the individual dose should be adjusted to find the lowest effective dose. The lowest effective dose should be maintained for long-term treatment. In case of a relapse, the dose should be increased to 2 mg ephedrine hydrochloride per kg BW again. Once the effective dose has been established, dogs should still be monitored at regular intervals.

This tablet strength is not appropriate for dogs weighing less than 12.5 kg (recommended starting dose of 2 mg/kg).

9. Advice on correct administration

Tablets can be divided into 2 equal parts to ensure accurate dosing.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the blisters in the outer carton in order to protect from light. Do not refrigerate or freeze.

Unused divided tablets should be returned to the blister and used in the subsequent dose.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton 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 57446/4020

Package size: Cardboard box containing 10 blisters of 10 tablets each.

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 manufacturer responsible for batch release and contact details to report suspected adverse events:

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

Tel: +43 (0)664 8455326

E-mail: adverse.events@vetviva.com

17. Other information

POM-V	Veterinary medicinal product subject to prescription.
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Approved 12 February 2025

Gavin Hall