SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Caniphedrin 50 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Ephedrine hydrochloride 50 mg
(equivalent to 41.0 mg Ephedrine)

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets

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

4. CLINICAL PARTICULARS

4.1 Target species

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 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 4.8).
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

It is not appropriate to use the 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.

4.5 Special precautions for use

Special precautions for use in animals
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.

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 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 gloves for administration.
Wash hands thoroughly after administration of the product.

4.6 Adverse reactions (frequency and seriousness)

In rare cases increased pulse frequency, ventricular arrhythmia and central nervous excitation have been observed. These symptoms disappear following dose reduction or termination of treatment.

Due to the pharmacological properties of ephedrine the following effects can occur at the recommended therapeutic dose:
- 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).
- Mydriasis
- Bronchodilatation and decrease of mucus release in the respiratory mucosal membranes.
- Reduction of the motility and tone of the intestinal wall.

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

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 arrhythmia when combined with cardiac glycosides (e.g. digoxin), quinine, tricyclic antidepressants and halogenated narcotics (see section 4.3).
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.

4.9 Amounts to be administered and administration route

For 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).

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

At high overdoses, the following undesirable effects 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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: urologicals, ephedrine
ATCvet 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 sympathic 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 sympathicomimetic action on the adrenergic receptors.

5.2 Pharmacokinetic particulars

After oral administration it is rapidly and practically completely absorbed, whereby peak plasma levels are achieved after one hour. Ephedrine is rapidly distributed in all tissues and can also gradually penetrate the CNS. Ephedrine is not degraded via the endogenous catecholamine pathways, which explains the prolonged duration of activity compared to adrenaline. N-demethylation generates norephedrine as the major metabolite, a potent metabolite that is formed very rapidly in dogs and appears to contribute significantly to the effect of ephedrine. Elimination takes place via the kidneys and is nearly completed after 24 hours. The half-life is 3 to 6 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin
Potato starch
Lactose monohydrate
Talc
Cellulose, microcrystalline
Glycerol 85 %

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Unused divided tablets should be returned to the blister and used in the subsequent dose.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Heat-sealed blister pack, consisting of aluminium foil and a PVC foil with 10 tablets per blister.

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

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Richter Pharma AG
Feldgasse 19
4600 Wels
Austria

8. MARKETING AUTHORISATION NUMBER

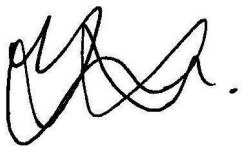
Vm 22080/4022

9. DATE OF FIRST AUTHORISATION

05 August 2020

10. DATE OF REVISION OF THE TEXT

June 2022



Approved: 21 June 2022