1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diazedor 5 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Diazepam 5.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Ethanol 96%
Propylene glycol
Sodium hydroxide (for pH adjustment)
Water for injections

Clear, colourless to greenish-yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats

3.2 Indications for use for each target species

Dogs, cats:
For the short-term management of convulsive disorders and skeletal muscle spasms of central and peripheral origin.
As part of a pre-anaesthetic or sedation protocol.

3.3 Contraindications

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

3.4 Special warnings

- For strict intravenous use.
- Diazepam alone is less likely to be effective as a sedative when used in animals that are already excited.
- Diazepam can cause sedation and disorientation and should be used with caution in working animals, such as military, police or service dogs.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal product should be used with caution in animals with hepatic or renal disease and in debilitated, dehydrated, anaemic, obese, or geriatric animals.

The veterinary medicinal product should be used with caution in animals in shock, coma, or with significant respiratory depression.
The veterinary medicinal product should be used with caution in animals affected by glaucoma.
It is not recommended to use diazepam for convulsive disorder control in cats in case of chronic chlorpyrifos toxicosis as organophosphate's toxicity may be potentiated.

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

This veterinary medicinal product is a CNS depressant. Avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive, as sedation may occur.
People with known hypersensitivity to diazepam, other benzodiazepines or any of the excipients should avoid contact with the veterinary medicinal product.

The veterinary medicinal product can cause skin irritation. Avoid contact with skin. In case of accidental spillage onto skin, wash with soap and water. If irritation persists, seek medical advice.

The veterinary medicinal product can cause eye irritation. Avoid contact with eyes. If the veterinary medicinal product comes into contact with the eyes, rinse the eyes immediately with plenty of water and seek medical attention if irritation persists.

Diazepam may be harmful for the foetus and unborn child. Diazepam and its metabolites are secreted into milk, thereby exerting a pharmacological effect on the nursing neonate. As such, women of child-bearing potential and nursing mothers should not handle this veterinary medicinal product.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs, cats:

Rare (1 to 10 animals / 10 000 animals treated):	Excitation[1], Aggression[1], Disinhibiting effect[1].
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Acute hepatic necrosis[2], Liver failure[2].
Undetermined frequency (cannot be estimated from the available data):	Hypotension[3], Cardiac disorder[3], Thrombophlebitis[3]; Increased appetite[4]; Ataxia, Disorientation, Mental impairment; Behavioural disorder.

[1] Paradoxical reactions may be observed mainly in small breeds of dogs. Therefore, avoid use of diazepam as a sole agent in potentially aggressive animals.
[2] Only in cats.
[3] Associated with rapid intravenous administration.
[4] Mainly in cats.

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 its local representative 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

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.
If used in lactating females, puppies/kittens should be monitored carefully for undesired somnolence/sedative effects that could interfere with suckling.

3.8 Interaction with other medicinal products and other forms of interaction

Diazepam is a central nervous system depressant which may potentiate the action of other central nervous system depressants as barbiturates, tranquilizers, narcotics or antidepressants.
Diazepam may enhance the action of digoxin.
Cimetidine, erythromycin, azole substances (such as itraconazole or ketoconazole), valproic acid and propranolol may slow the metabolism of diazepam. The dose of diazepam may need to be decreased to avoid excessive sedation.
Dexamethasone may decrease the action of diazepam.
The concomitant use with hepatotoxic dosages of other substances should be avoided.

3.9 Administration routes and dosage

For slow intravenous use only.
To ensure a correct dosage, body weight should be determined as accurately as possible.

Dogs, cats:
- Short term management of convulsive disorders: 0.5 - 1.0 mg diazepam/kg bodyweight (equivalent to 0.5 - 1.0 ml/5 kg). Administered as a bolus and repeated up to three times, after no less than 10 minutes each time.
- Short term management of skeletal muscle spasm: 0.5 - 2.0 mg/kg bodyweight (equivalent to 0.5 - 2.0 ml/5 kg).
- As part of sedation protocol: 0.2 - 0.6 mg/kg bodyweight (equivalent to 0.2 - 0.6 ml/5 kg).
- As part of pre-anaesthesia protocol: 0.1 - 0.2 mg/kg bodyweight (equivalent to 0.1 - 0.2 ml/5 kg).

The rubber stopper may be safely punctured up to 100 times. (Broaching study was performed with a 23G injection needle.)

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

When administered alone, diazepam overdose may cause significant central nervous system depression (confusion, decreased reflexes, coma, etc). Supportive treatment should be given (cardio-respiratory stimulation, oxygen). Hypotension and respiratory and cardiac depression are rare events.

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

For administration by a veterinarian or under their direct supervision.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN05BA01

4.2 Pharmacodynamics

Diazepam is a sedative and muscle relaxant of the benzodiazepine family that binds to the benzodiazepine binding domain of $GABA_A$ receptors and thus enhances the inhibitory effect of GABA. This mechanism produces sedative, anxiolytic, myorelaxant and anticonvulsive effects.

4.3 Pharmacokinetics

Diazepam is highly lipid soluble and is widely distributed throughout the body. It readily crosses the blood-brain barrier and is highly bound to plasma proteins. It is metabolised in the liver to produce several pharmacologically active metabolites (major metabolite in dogs is N-desmethyl-diazepam), which are conjugated with glucuronide and eliminated primarily in the urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale in 2 ml ampoule: 3 years.
Shelf-life of the veterinary medicinal product as packaged for sale in 10 ml vial: 30 months.

Shelf life after first opening the immediate packaging (2 ml): Use immediately. Discard any unused material.
Shelf life after first opening the immediate packaging (10 ml): 56 days.

5.3 Special precautions for storage

Keep the ampoules/vial in the outer carton in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.

5.4 Nature and composition of immediate packaging

Colourless glass ampoules, type I, with 2 ml solution for injection or colourless glass vials, type I, with 10 ml solution for injection, closed with a chlorobutyl rubber stopper and either an aluminium pull off cap or an aluminium/plastic flip off cap.

Pack sizes: 5 x 2 ml, 10 x 2 ml ampoules and 1 x 10 ml vial in a cardboard box.

Not all pack sizes may be marketed.

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 or household waste.

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

VetViva Richter GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA23462/008/001

8. DATE OF FIRST AUTHORISATION

01 June 2018

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

14 February 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary)