Summary of Product Characteristics

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 substance:
Diazepam 5.0 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection
Clear, colourless to greenish-yellow solution

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats

4.2 Indications for use, specifying the target species

In cats and dogs:
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.

4.3 Contraindications

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

4.4 Special warnings for each target species

- 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.

4.5 Special precautions for use

Special precautions for use in animals

The product should be used with caution in animals with hepatic or renal disease and in debilitated, dehydrated, anaemic, obese, or geriatric animals.
The product should be used with caution in animals in shock, coma, or with significant respiratory depression.
The 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 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 product can cause skin irritation. Avoid contact with skin. In the case of contact with skin, wash with soap and water. If irritation persists, seek medical advice.

The product can cause eye irritation. Avoid contact with eyes. If the 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 product.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Rapid intravenous administration may cause hypotension, cardiac disorders and thrombophlebitis.
In rare cases, mainly in small breeds of dogs, paradoxical reactions may be observed (as excitation, aggression or disinhibiting effect), therefore, avoid use of diazepam as a sole agent in potentially aggressive animals. In very rare cases (less than 1 animal in

10,000 animals treated, including isolated reports) the use of diazepam in cats can cause acute hepatic necrosis and liver failure.
Other reported effects include increased appetite (mainly in cats), ataxia, disorientation, changes in mentation and behaviour.

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

Use of the product for the target species during pregnancy and lactation has not been investigated therefore use must be 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.

4.8 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 propanol 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.

4.9 Amounts to be administered and administration route

For administration by slow, intravenous injection only.

In dogs and 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/5kg).

- As part of sedation protocol: 0.2 - 0.6 mg/kg bodyweight (equivalent to 0.2 - 0.6 ml/5kg).
- As part of pre-anaesthesia protocol: 0.1 - 0.2 mg/kg bodyweight (equivalent to 0.1 - 0.2 ml/5kg).

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

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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Psycholeptics, benzodiazepine derivatives, diazepam
ATCvet code: QN05BA01

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96%
Propylene glycol
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: Use immediately.
Discard any unused material.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Cardboard box with colourless glass ampoules with a nominal volume of 2 ml.

Pack sizes: 5 x 2 ml
10 x 2 ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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(S)

VPA10801/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st June 2018

10 DATE OF REVISION OF THE TEXT