SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZIAPAM, 5 mg/ml, solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains:

Active substance:
Diazepam ..... 5.0 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl Alcohol (E1519)	15.7 mg
Benzoic Acid (E210)	2.5 mg
Sodium Benzoate (E211)	47.5 mg
Propylene Glycol	
Ethanol (96 per cent)	
Sodium hydroxide (for pH adjustment)	
Water for injections	

Solution for injection.
Greenish-yellow clear liquid .

3. CLINICAL INFORMATION

3.1 Target species

Dog and cat

3.2 Indications for use for each target species

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 intravenous use only.
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 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:

People with known sensitivity to diazepam or 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.
Wash hands after use.
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.
This product is a CNS depressant. Take care to avoid accidental self-injection. If accidental self-injection occurs, seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive, as sedation may occur.
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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats :

Rare (1 to 10 animals / 10,000 animals treated):	Behavioural disorders (e.g. excitation, aggression, disinhibiting effect) [1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hepatic necrosis (acute) [2], liver failure [2]
Undetermined frequency	Hypotension [3], cardiac disorders [3], thrombophlebitis [3] Ataxia, disorientation, changes in mentation and behaviour Increased appetite [4]

[1] Paradoxical reactions. Mainly in small breeds of dogs. Avoid use of diazepam as a sole agent in potentially aggressive animals.
[2] In cats only.
[3] May be caused by 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 section “contact details”of the package leaflet.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in cats and dogs.
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, antidepressants…
Diazepam may increase 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.

3.9 Administration routes and dosage

For administration by slow, intravenous injection only.

In dogs and cats:
Short term management of convulsive disorders: 0.5 mg diazepam/kg bodyweight (equivalent to 0.5 ml/5kg).
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).

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

Not applicable.
[For MRP/DCP/SRP and national procedures: To be completed nationally.]”

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN05BA01

4.2 Pharmacodynamics

Diazepam is a benzodiazepine derivative thought to depress the sub-cortical levels of the central nervous system (primarily limbic, thalamic and hypothalamic) to produce anxiolytic, sedative, musculosketetal relaxant and anticonvulsant effects. The exact mechanism of action has not been defined.

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 metabolized 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: 4 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store in the original package. Protect from light.
Any solution remaining in the ampoule following withdrawal of the required dose should be discarded.

5.4 Nature and composition of immediate packaging

Cardboard box of 6 colourless glass ampoules type I of 2 ml.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Domes Pharma

7. MARKETING AUTHORISATION NUMBER

Vm 54982/3005

8. DATE OF FIRST AUTHORISATION

05 March 2014

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

November 2023

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).

Approved 16 November 2023