SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml 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)	
Sodium Benzoate (E211)	
Propylene Glycol	
Ethanol (96 per cent)	
Water for injections	

Clear, yellow-green solution , pH 6.2-7.2

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

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

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 poisoning by pesticides (chlorpyrifos) as the toxicity of these organophosphates may be potentiated.
Paradoxical reactions (including excitation, a disinhibiting effect and aggression) may be observed if diazepam is used as a sole agent, therefore avoid the use of diazepam alone in potentially aggressive animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Diazepam is a CNS depressant and can cause sedation and induction of sleep. Care should be taken to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician, but DO NOT DRIVE as sedation and impaired muscular function may occur.
Diazepam and its metabolites may be harmful for the unborn child, and are secreted into breastmilk in small amounts, thereby exerting a pharmacological effect on the nursing neonate. Pregnant women or women intending to become pregnant and breastfeeding women should, therefore, avoid handling or take great care when handling this product and, in the event of exposure, seek medical advice immediately.
People with known hypersensitivity to diazepam or the excipients should avoid contact with the veterinary medicinal product.
This product contains benzyl alcohol and 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.

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):	Paradoxical effects (e.g. excitation, aggression, disinhibiting effect)[a]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hepatic necrosis (acute)[b], liver failure[b]
Undetermined frequency	Hypotension[c], cardiac disorders[c], thrombophlebitis[c] Ataxia, disorientation, changes in mentation and behaviour Increased appetite[d]

[a] Mainly in small breeds of dogs.
[b] In cats only.
[c] May be caused by rapid intravenous administration.
[d] 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 also section “Contact details” of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Laboratory studies in mice and hamsters have shown evidence of teratogenic effects at high maternotoxic doses. Rodent studies have indicated that prenatal exposure to diazepam at clinical doses can produce long-term changes in cellular immune responses, brain neurochemistry and behaviour.
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.

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 such as barbiturates, tranquilizers, narcotics and 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

Intravenous use.
For slow intravenous injection only.

Short term management of convulsive disorders: 0.5-1.0 mg diazepam/kg bodyweight (equivalent to 0.5-1.0 ml/5kg). Administered as a slow 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).

The vial may be safely punctured up to 100 times.

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

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

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, musculoskeletal 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 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: 2 years
Shelf life after first opening the immediate packaging: 56 days

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Cardboard box with one clear type I glass vial containing 5 ml, 10 ml, 20 ml or 50 ml with a coated bromobutyl rubber stopper and aluminium cap.

Pack sizes:
Box with 1 vial of 5 ml
Box with 1 vial of 10 ml
Box with 1 vial of 20 ml
Box with 1 vial of 50 ml

Multi-pack with 6 boxes each containing 1 vial of 5 mL
Multi-pack with 6 boxes each containing 1 vial of 10 mL
Multi-pack with 6 boxes each containing 1 vial of 20 mL

Multi-pack with 10 boxes each containing 1 vial of 5 mL
Multi-pack with 10 boxes each containing 1 vial of 10 mL
Multi-pack with 10 boxes each containing 1 vial of 20 mL

Not all pack sizes may be marketed.

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

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBER

50406/3001

8. DATE OF FIRST AUTHORISATION

20 February 2019

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

30 June 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 30 June 2023