PARTICULARS TO APPEAR ON THE OUTER PACKAGE { Cardboard box }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZIAPAM, 5 mg/ml, solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of solution contains:

Active substance:

Diazepam 5.0 mg

Excipients:

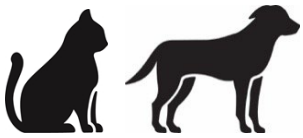
Benzyl Alcohol (E1519)	15.7 mg
Benzoic Acid (E210)	2.5 mg
Sodium Benzoate (E211)	47.5 mg

3. PACKAGE SIZE

6 x 2 ml

4. TARGET SPECIES

Dog and cat



5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Slow intravenous injection only.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package. Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

DOMES PHARMA
3 rue André Citroën
63430 Pont-du-Château
France

Local representative:

TVM UK Animal Health Ltd
Building B, Kirtlington Business Centre
Kirtlington
Oxfordshire
OX5 3JA
United Kingdom

Customer service : help@tvm-uk.com

14. MARKETING AUTHORISATION NUMBER

Vm 54982/5005

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

User warnings: Diazepam may be harmful for the foetus and unborn child. Pregnant and breast-feeding women should not handle this product. See package leaflet for full user warnings.'

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

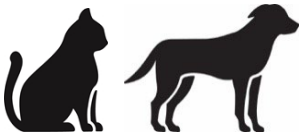
18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Label - Colourless glass ampoules type I of 2 ml }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZIAPAM 5 mg/ml, solution for injection



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {month/year}

Once opened use immediately.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

2 ml

6. ROUTE(S) OF ADMINISTRATION

Intravenous use

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

1 ml contains:
Diazepam 5.0 mg
Benzyl Alcohol (E1519) 15.7 mg
Benzoic Acid (E210) 2.5 mg
Sodium Benzoate (E211) 47.5 mg

Solution for injection.
Greenish-yellow clear liquid.

3. TARGET SPECIES

Dog and cat

4. INDICATIONS FOR USE

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.

5. 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.

6. SPECIAL WARNING(S)

Special warnings:

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.

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.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in cats and dogs. 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.

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.

Overdose:

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.

Major Incompatibilities:

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

For Animal Treatment Only

Keep out of sight and reach of children.

7. ADVERSE EVENTS

Dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Behavioural disorders (e.g. excitation, aggression, desinhibiting 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], and thrombophlebitis [3] Ataxia, disorientation, change 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to either the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system <{national system details}.>

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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).

9. ADVICE ON CORRECT ADMINISTRATION

Administration by slow, intravenous injection only.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in the original package. Protect from light.

Any solution remaining in the ampoule following withdrawal of the required dose should be discarded.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Use immediately after opening.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

POM-V

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation number:

Vm 54982/5005

Pack sizes:

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

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

November 2023

16. CONTACT DETAILS

Marketing authorisation holder

DOMES PHARMA
3 rue André Citroën
63430 Pont-du-Château
France

Manufacturer responsible for batch release:

CENEXI
52 rue Marcel et Jacques Gaucher
94120 Fontenay-sous-Bois
France

Local representatives and contact details to report suspected adverse reactions :

TVM UK Animal Health Ltd
United Kingdom

Customer service : help@tvm-uk.com

Approved 16 November 2023