# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZIAPAM, 5 mg/ml, solution for injection for dogs and cats (UK(NI))
ZIAPAM, 5 mg/ml, Injektionslösung für Hunde und Katzen (AT, BE, DE)
ZIAPAM, 5 mg/ml, solution injectable pour chiens et chats (BE)
ZIAPAM, 5 mg/ml, oplossing voor injectie voor honden en katten (BE, NL)
ZIAPAM, 5 mg/ml, solucion inyectable para perros y gatos (ES)
DIAZEPAM TVM, 5 mg/ml, solution injectable pour chiens et chats (FR)
ZIAPAM, 5 mg/ml, soluzione iniettabile per cani e gatti (IT)
ZIAPAM, 5 mg/ml, roztwór do wstrzykiwań dla psów i kotów (PL)
ZIAPAM, 5 mg/ml, solução injetável para cães e gatos (PT)

## 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<br>(1 to 10 animals / 10,000 animals treated): | Behavioural disorders (e.g. excitation, aggression, disinhibiting effect) [1] |
| Very rare<br>(<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]<br>Ataxia, disorientation, changes in mentation and behaviour<br>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(S)

AT: Zul.-Nr.: 835471
BE: BE-V457137
DE : Zul.-Nr.: 401975.00.00
ES : 2983 ESP
FR : FR/V/3626480 1/2014
IT: AIC n. 104625013
NL: REG NL 113493
PL: 2807/18
PT: 770/01/14DFVPT
UK(NI): Vm 54982/3005

## 8. DATE OF FIRST AUTHORISATION

AT: 20/03/2014
BE: 16/04/2014
DE : 10/03/2014
ES : 18/02/2014
FR : 13/02/2014
IT: 17/04/2014
NL: 17/03/2014
PL: 28/08/2018
PT: 05/02/2014
UK: 05/03/2014

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

XX/XX/XXXX

## 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).

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**
**{carton box}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZIAPAM 5 mg/ml solution for injection (UK(NI))
ZIAPAM 5 mg/ml Injektionslösung (AT, BE, DE)
ZIAPAM 5 mg/ml solution injectable (BE)
ZIAPAM 5 mg/ml oplossing voor injectie (BE, NL)
ZIAPAM 5 mg/ml solucion inyectable (ES)
DIAZEPAM TVM 5 mg/ml solution injectable (FR)
ZIAPAM 5 mg/ml soluzione iniettabile (IT)
ZIAPAM 5 mg/ml roztwór do wstrzykiwań (PL)
ZIAPAM 5 mg/ml solução injetável (PT)

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of solution contains:

Diazepam ..... 5.0 mg

## 3. PACKAGE SIZE

6 x 2 ml

## 4. TARGET SPECIES

Dog and cat

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Slow intravenous injection only.

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp. {month/year}
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 OF THE MARKETING AUTHORISATION HOLDER

DOMES PHARMA

## 14. MARKETING AUTHORISATION NUMBERS

AT: Zul.-Nr.: 835471
BE: BE-V457137
DE : Zul.-Nr.: 401975.00.00
ES : 2983 ESP
FR : FR/V/3626480 1/2014
IT: AIC n. 104625013
NL: REG NL 113493
PL: 2807/18
PT: 770/01/14DFVPT
UK(NI): Vm 54982/3005

## 15. BATCH NUMBER

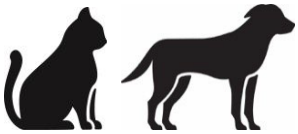
Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**{** label - **Colourless glass ampoule type I of 2 ml}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZIAPAM (UK(NI), AT, BE, DE, NL, ES, IT, PL, PT)
DIAZEPAM TVM (FR)



## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

5 mg/ml

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {month/year}
Once opened use immediately.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

ZIAPAM, 5 mg/ml, solution for injection for dogs and cats (UK(NI))
ZIAPAM, 5 mg/ml, Injektionslösung für Hunde und Katzen (AT, BE, DE)
ZIAPAM, 5 mg/ml, solution injectable pour chiens et chats (BE)
ZIAPAM, 5 mg/ml, oplossing voor injectie voor honden en katten (BE, NL)
ZIAPAM, 5 mg/ml, solucion inyectable para perros y gatos (ES)
DIAZEPAM TVM, 5 mg/ml, solution injectable pour chiens et chats (FR)
ZIAPAM, 5 mg/ml, soluzione iniettabile per cani e gatti (IT)
ZIAPAM, 5 mg/ml, roztwór do wstrzykiwań dla psów i kotów (PL)
ZIAPAM, 5 mg/ml, solução injetável para cães e gatos (PT)

## 2. Composition

Each ml of solution 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 warnings

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.

## 7. Adverse events

In 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], and 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] M ainly 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, routes 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 periods

Not applicable.

## 11. Special storage precautions

Keep out of the sight and reach or 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 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 applicable national collection systems. These measures should help to protect the environment.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers:
AT: Zul.-Nr.: 835471
BE: BE-V457137
DE : Zul.-Nr.: 401975.00.00
ES : 2983 ESP
FR : FR/V/3626480 1/2014
IT: AIC n. 104625013
NL: REG NL 113493
PL: 2807/18
PT: 770/01/14DFVPT
UK(NI): Vm 54982/4005

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

## 15. Date on which the package leaflet was last revised

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

## 16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
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> :

**<17. Other information>**

[For MRP/DCP/SRP and national procedures: To be completed nationally.]”