PARTICULARS TO APPEAR ON THE OUTER PACKAGE
cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 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

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

Box of 6 ampoules of 2 ml

5. TARGET SPECIES

Cats, dogs.

6. INDICATION

7. METHOD AND ROUTE OF ADMINISTRATION

For administration by slow, intravenous injection only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

Accidental self-injection is dangerous, read package leaflet before use. Due to this risk, pregnant women and nursing mothers should not handle this product. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Use immediately after opening.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Domes Pharma
3 Rue Andre Citroen
63430 Pont-du-Chateau
France

16. MARKETING AUTHORISATION NUMBER

Vm 54982/4005

17. MANUFACTURER'S BATCH NUMBER

<Lot> {number}

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE

5 mg/ml (10 mg/ampoule)

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

Ampoule of 2 ml

4. ROUTE OF ADMINISTRATION

Intravenous use

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

<Lot> {number}

7. EXPIRY DATE

<EXP> {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE INSERT

PACKAGE LEAFLET FOR:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Domes Pharma
3 Rue Andre Citroen
63430 Pont-du-Chateau
France

Manufacturer responsible for batch release:
CENEXI
52 rue Marcel et Jacques Gaucher
94120 Fontenay sous bois
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 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
Greenish-yellow clear liquid.

4. INDICATION

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.

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. ADVERSE REACTIONS

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, disinhibiting effect …), therefore, avoid use of diazepam as a sole agent in potentially aggressive animals.
In very rare cases 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. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

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).

Alternatively you can report via your national reporting system {xxx}.

7. TARGET SPECIES

Cats, dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE 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

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light.

Any solution remaining in the ampoule following withdrawal of the required dose should be discarded.
Shelf life of the veterinary medicinal product as packaged for sale: 4 years. Do not use after the expiry date stated on the label after EXP. The expiry date refers to the last day of that month.
Use immediately after opening.
Keep out of the sight and reach of children.

12. SPECIAL WARNINGS

Special warnings for each target species:
For strict IV 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.

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:
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.

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.

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 (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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2022

15. OTHER INFORMATION

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

Marketing authorization numbers:
Vm 54982/4005

Classification of the medicinal product in terms of dispensing:
For animal treatment only. To be supplied only on veterinary prescription.

Approved 04 March 2022