[Version 8.1 01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diazedor 5 mg/ml solution for injection for dogs and cats
(AT, DE, ES, FR, IE, IT, NL, PT, UK)

Diazedor vet. 5 mg/ml solution for injection for dogs and cats
(DK, FI, NO, SE)

Diazedin 5 mg/ml solution for injection for dogs and cats
(BE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Diazepam 5.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear, colourless to greenish-yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of severe hepatic disease.

4.4 Special warnings for each target species

- For strict intravenous 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.

4.5 Special precautions for use

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

This product is a CNS depressant. Avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive, as sedation may occur.
People with known hypersensitivity to diazepam, other benzodiazepines or any of 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.

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.

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.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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 or disinhibiting effect), therefore, avoid use of diazepam as a sole agent in potentially aggressive animals. In very rare cases (less than 1 animal in 10,000 animals treated, including isolated reports) 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.

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).

4.7 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.

4.8 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 or antidepressants.
Diazepam may enhance 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.

4.9 Amounts to be administered and administration route

For administration by slow, intravenous injection only.

In dogs and cats:
- Short term management of convulsive disorders: 0.5 - 1.0 mg diazepam/kg bodyweight (equivalent to 0.5 - 1.0 ml/5 kg).
- 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).

4.10 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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Psycholeptics, benzodiazepine derivatives, diazepam
ATCvet code: QN05BA01

5.1 Pharmacodynamic properties

Diazepam is a sedative and muscle relaxant of the benzodiazepine family that binds to the benzodiazepine binding domain of $GABA_A$ receptors and thus enhances the inhibitory effect of GABA. This mechanism produces sedative, anxiolytic, myorelaxant and anticonvulsive effects.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96%
Propylene glycol
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: Use immediately.
Discard any unused material.

6.4. Special precautions for storage

Keep the ampoules in the outer carton in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.

6.5 Nature and composition of immediate packaging

Cardboard box with colourless glass ampoules with a nominal volume of 2 ml.

Pack sizes: 5 x 2 ml
10 x 2 ml
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diazedor 5 mg/ml solution for injection for dogs and cats
(AT, DE, ES, FR, IE, IT, NL, PT, UK)

Diazedor vet. 5 mg/ml solution for injection for dogs and cats
(DK, FI, NO, SE)

Diazedin 5 mg/ml solution for injection for dogs and cats
(BE)

diazepam

2. STATEMENT OF ACTIVE SUBSTANCES

Diazepam 5.0 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5 x 2 ml
10 x 2 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

-

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Keep the ampoules in the outer carton in order to protect from light.

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

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Clear glass vial 2 ml

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(DK, FI, NO, SE)

Diazedin 5 mg/ml injection for dogs and cats
(BE)

diazepam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

5.0 mg/ml

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

2 ml

4. ROUTE(S) OF ADMINISTRATION

IV

5. WITHDRAWAL PERIOD(S)

-

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Diazedor 5 mg/ml solution for injection for dogs and cats
(AT, DE, ES, FR, IE, IT, NL, PT, UK)

Diazedor vet. 5 mg/ml solution for injection for dogs and cats
(DK, FI, NO, SE)

Diazedin 5 mg/ml solution for injection for dogs and cats
(BE)

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

Marketing authorisation holder and manufacturer responsible for batch release:
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diazedor 5 mg/ml solution for injection for dogs and cats
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(DK, FI, NO, SE)

Diazedin 5 mg/ml solution for injection for dogs and cats
(BE)

diazepam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:
Diazepam 5.0 mg

Clear, colourless to greenish-yellow solution

4. INDICATION(S)

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 known 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 or disinhibiting effect), therefore, avoid use of diazepam as a sole agent in potentially aggressive animals. In very rare cases (less than 1 animal in 10,000 animals treated, including isolated reports) 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.

The frequency of adverse reactions is defined using the following convention:
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- 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).

If you notice any side effects, even those not already listed in this package leaflet/label or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats.

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

For administration by slow, intravenous injection only.

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- Short term management of convulsive disorders: 0.5 - 1.0 mg diazepam/kg bodyweight
- (equivalent to 0.5 - 1.0 ml/5 kg).
- 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/5 kg).
- As part of sedation protocol: 0.2 - 0.6 mg/kg bodyweight (equivalent to 0.2 - 0.6 ml/5 kg).
- As part of pre-anaesthesia protocol: 0.1 - 0.2 mg/kg bodyweight (equivalent to 0.1 - 0.2 ml/5 kg).

This product does not contain an antimicrobial preservative. Use the ampoule on one occasion only. Discard any unused material.

9. ADVICE ON CORRECT ADMINISTRATION

Administer the product slowly.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the ampoules in the outer carton in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after “EXP”. The expiry date refers to the last day of that month.
Shelf life after first opening the container: Use immediately

12. SPECIAL WARNING(S)

Special warnings for each target species
- For strict intravenous 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
This product is a CNS depressant. Avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive, as sedation may occur.
People with known hypersensitivity to diazepam, other benzodiazepines or any of 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.

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.

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.

Wash hands after use.

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 or antidepressants.
Diazepam may enhance 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)
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 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 product should be disposed in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD/MM/YYYY}

15. OTHER INFORMATION

Pack sizes: 5 x 2 ml
10 x 2 ml
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.