ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Outer carton
Multi-pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tralieve 50 mg/ml solution for injection for dogs
Tramadol hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Tramadol hydrochloride 50 mg, equivalent to 43.9 mg tramadol

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 x 10 ml
1 x 20 ml
1 x 50 ml
6 x 10 ml
6 x 20 ml
6 x 50 ml
10 x 10 ml
10 x 20 ml
10 x 50 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous or intramuscular 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}
Shelf life after first opening the container: 8 weeks
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

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.
Supply / use: (National issue)

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

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41821/4055

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vials of 10, 20 or 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tralieve 50 mg/ml solution for injection
Tramadol hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

50 mg/ml

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

10 ml
20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

IV, IM

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 8 weeks
Once broached use by ……..

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Tralieve 50 mg/ml solution for injection for 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:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tralieve 50 mg/ml solution for injection for dogs
tramadol hydrochloride

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

1 ml contains:
Active substance:
Tramadol hydrochloride 50 mg
(equivalent to 43.9 mg tramadol)

Excipients:
Benzyl alcohol (E1519) 10 mg

Clear and colourless solution.

4. INDICATION(S)

For the reduction of mild postoperative pain.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or any of the excipients.

Do not administer in conjunction with tricyclic antidepressants, monoamine oxidase inhibitors and serotonin reuptake inhibitors.
Do not use in animals with epilepsy.

6. ADVERSE REACTIONS

Nausea and vomiting have occasionally been observed in dogs after administration of tramadol. In rare cases (more than 1 but less than 10 animals in 10,000 animals treated) hypersensitivity can occur. In cases of hypersensitivity reactions the treatment should be discontinued.
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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

For intramuscular or intravenous injection: 2−4 mg tramadol hydrochloride per kg bodyweight, corresponding to 0.04−0.08 ml product per kg bodyweight.
Repeat doses can be administered every 6 to 8 hours (3-4 times daily). The recommended maximum daily dose is 16 mg/kg.
Intravenous administration must be carried out very slowly.
As the individual response to tramadol is variable, and depends partly on the dosage, the age of the patient, individual differences in pain sensitivity and general condition, the optimal dosing regimen should be individually tailored using the above dose and re-treatment interval ranges. In the event of the product failing to provide adequate analgesia by 30 minutes following administration or for the duration of any planned re-treatment interval, a suitable alternative analgesic should be used.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 8 weeks

12. SPECIAL WARNING(S)

Special warnings for each target species:
The analgesic effects of tramadol hydrochloride may be variable. This is thought to be due to individual differences in the metabolism of the drug to the primary active metabolite O-desmethyltramadol. In some dogs (non-responders) this may result in the medicinal product failing to provide analgesia. Dogs should therefore be monitored regularly to ensure sufficient efficacy.

Special precautions for use in animals:
Use with caution in dogs with renal or hepatic impairment. In dogs with hepatic impairment the metabolism of tramadol to the active metabolites may be decreased which may reduce the efficacy of the medicinal product. One of the active metabolites of tramadol is renally excreted and therefore in dogs with renal impairment the dosing regimen used may need to be adjusted. Renal and hepatic function should be monitored when using this medicinal product. See also section on Interactions.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to tramadol or any of the excipients should avoid contact with the veterinary medicinal product.
The product may cause skin and eye-irritation. Avoid contact with the skin and eyes. Wash hands after use. In case of accidental eye exposure, rinse with clean water.
There is inadequate evidence available on the safety of tramadol in human pregnancy. Pregnant women and women of childbearing age should therefore take great care when handling this product and, in the event of exposure, seek medical advice immediately.
Tramadol may cause nausea and dizziness following accidental self-injection. If you develop symptoms following accidental exposure, seek medical advice and show the package leaflet or the label to the physician. However, DO NOT DRIVE as sedation may occur.

Pregnancy:
Laboratory studies in mice and/or rats and rabbits have not produced any evidence of teratogenic, foetotoxic, maternotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Lactation:
Laboratory studies in mice and/or rats and rabbits have not produced any evidence of adverse effects in the peri- and postnatal development of offspring. Use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:
In laboratory studies in mice and/or rats and rabbits, the use of tramadol at therapeutic doses did not adversely affect reproductive performance and fertility in males and females. Use only according to the benefit-risk assessment by the responsible veterinarian.

Overdose (symptoms, emergency procedures, antidotes):
In cases of intoxication with tramadol symptoms similar to those observed with other centrally acting analgesics (opioids) are likely to occur. This include in particular miosis, vomiting, cardiovascular collapse, consciousness disorders up to coma, convulsions and respiratory depression up to respiratory arrest.
General emergency measures: Maintain a patent airway; support cardiac and respiratory function depending on the symptoms. The antidote for respiratory depression is naloxone. However, the decision to use naloxone in the event of an overdose should be made following an assessment of the benefit-risk ratio for the individual as it may only partially reverse some of the other effects of tramadol and may increase the risk of seizures, although data on the latter are conflicting. In case of seizures, administer diazepam.

Interaction with other medicinal products and other forms of interaction:
Concomitant administration of the product with central nervous system depressants may potentiate the CNS and respiratory depressant effects.
When the product is administered together with medicinal products with a sedative effect, the duration of sedation may be increased.
Tramadol can induce convulsions and increase the effect of drugs that lower the seizure threshold.
Drugs that inhibit (e.g. cimetidine and erythromycin) or induce (e.g. carbamazepine) CYP450 mediated metabolism may have an effect on the analgesic effect of tramadol. The clinical relevance of these interactions has not been studied in dogs.
See also section 5.

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

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

DD-MM-YYYY

15. OTHER INFORMATION

Pack sizes:
Cardboard box with 1 vial of 10 ml, 20 ml or 50 ml.
Multi-pack with 6 boxes each containing 1 vial of 10 ml, 20 ml or 50 ml.
Multi-pack with 10 boxes each containing 1 vial of 10 ml, 20 ml or 50 ml.
Not all pack sizes may be marketed.

Approved 23 June 2022