

ANNEX III
LABELLING AND PACKAGE LEAFLET

5.LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tralieve 50 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Tramadol 43.9 mg
(equivalent to 50 mg tramadol hydrochloride)

3. 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

4. TARGET SPECIES

Dogs.



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous or intramuscular use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the immediate packaging: 8 weeks.
Once broached use by ...

9. SPECIAL STORAGE PRECAUTIONS

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

Le Vet Beheer B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 41821/3018

15. 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



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Tramadol hydrochloride 50 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the immediate packaging: 8 weeks.
Once broached use by ...

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Tralieve 50 mg/ml solution for injection for dogs

2. Composition

Each ml contains:

Active substance:

Tramadol 43.9 mg
(equivalent to 50 mg tramadol hydrochloride)

Excipients:

Benzyl alcohol (E1519) 10 mg

Clear and colourless solution.

3. Target species

Dogs.

4. Indications for use

For the reduction of mild postoperative pain.

5. Contraindications

Do not use in animals with epilepsy.

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.

6. Special warnings

Special warnings:

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 veterinary medicinal product failing to provide analgesia. Dogs should therefore be monitored regularly to ensure sufficient efficacy.

Special precautions for safe use in the target species:

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 veterinary 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 veterinary 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 veterinary medicinal 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 veterinary medicinal 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.

Interaction with other medicinal products and other forms of interaction:

Concomitant administration of the veterinary medicinal product with central nervous system depressants may potentiate the CNS and respiratory depressant effects. When the veterinary medicinal product is administered together with veterinary 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 Contraindications.

Overdose:

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.

Major incompatibilities:

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

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction*
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting, nausea

*Treatment should be discontinued.

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 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

Intramuscular or intravenous use.

2–4 mg tramadol hydrochloride per kg bodyweight, corresponding to 0.04–0.08 ml veterinary medicinal 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 veterinary medicinal 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.

To ensure a correct dosage, body weight should be determined as accurately as possible.

9. Advice on correct administration

None.

10. Withdrawal periods

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 immediate packaging: 8 weeks.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 41821/3018

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

To be completed nationally.

Marketing authorisation holder <and manufacturer responsible for batch release>
<and contact details to report suspected adverse reactions>:

Manufacturer responsible for batch release:

Produlab Pharma B.V.

Forellenweg 16

4941 SJ Raamsdonksveer

The Netherlands

<Local representatives <and contact details to report suspected adverse reactions>:>

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

17. Other information

To be completed nationally.

Gavin Hall

Approved: 18 December 2024