ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramadog, 50 mg/ml, solution for injection for dogs
Tramadol hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml vial of solution contains:

Tramadol hydrochloride ..... 50.0 mg
(equivalent to 43.9 mg of tramadol base)

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

10 x 1 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

For the reduction of mild postoperative pain.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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}
Use immediately after opening.
Any solution remaining in the ampoule following withdrawal of the required dose should be discarded.

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any 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. 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 André Citroën
63430 PONT-DU-CHATEAU
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 54982/4009

17. MANUFACTURER'S BATCH NUMBER

<Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Ampoule sticker on colourless glass ampoules type I of 1 ml**}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRAMADOG, 50 mg/ml, solution for injection for dogs
Tramadol hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

50.0 mg/ml

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

1 ml

4. ROUTE(S) OF ADMINISTRATION

IM and IV

5. WITHDRAWAL PERIOD

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 FOR:

Tramadog, 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:
Domes Pharma
3 rue André Citroën
63430 Pont-du Chateau
France

Manufacturer responsible for batch release:
HAUPT PHARMA LIVRON
Rue du Comte de Sinard
26250 LIVRON SUR DRÔME
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRAMADOG, 50 mg/ml, solution for injection for dogs
Tramadol hydrochloride

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

Each 1 ml vial of solution contains:

Tramadol hydrochloride ..... 50.0 mg
(equivalent to 43.9 mg of tramadol base)

Clear, colourless liquid.

4. INDICATION(S)

For the reduction of mild postoperative pain.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to tramadol or to any of the excipients.
Do not use in dogs receiving concomitant treatment with tricyclic antidepressants, MAO inhibitors or serotonin reuptake inhibitors.
Do not use in animals with epilepsy.

6. ADVERSE REACTIONS

Nausea and vomiting may occasionally be observed following administration of the veterinary medicinal product. 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.
In the event that a reaction due to use of the medicinal product is observed, withdrawal of treatment is recommended.

If you notice any serious effects or other effects not mentioned in this package leaflet, 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.

Animals should be weighed to establish an accurate body weight prior to calculation of the appropriate treatment dose.

Route	Dose of tramadol (as hydrochloride)	Dose product
IV,IM	2-4 mg/kg bw *	0.04-0.08 ml/kg bw
Comments	*On the basis of the intensity of pain, repeat doses of tramadol 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

Intravenous administration must be carried out very slowly.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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: 48 months.
Shelf life after first opening the immediate packaging: Use immediately after opening.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

This veterinary medicinal product does not require any special storage conditions.

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

Special precautions for use in animals:
Use with caution care 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 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 product. See also section Interaction with other medicinal products and other forms of interaction.

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.
Tramadol may cause nausea and dizziness following injection. Avoid accidental self-injection. If you develop symptoms following exposure, seek medical advice and show the package leaflet or the label to the physician. However, DO NOT DRIVE as sedation may occur.
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.

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.
Tramadol may cause convulsions and intensify the effect of drugs that lower the convulsive threshold.
When the product is administered together with medicinal products with a sedative effect, the duration of sedation may be increased.
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.
The combination with mixed agonist/antagonists (e.g. buprenorphine, butorphanol) and tramadol is not advisable, because the analgesic effect of a pure agonist may be theoretically reduced in such circumstances.
See also section Contra-indications.

Overdose (symptoms, emergency procedures, antidotes):
In tramadol intoxication, symptoms similar to those observed with other centrally acting analgesics (opiates) are to be expected. These include, specifically, miosis, vomiting, cardiocirculatory collapse, disorders of consciousness including coma, convulsions and respiratory depression up to respiratory arrest.
General emergency measures: Maintain patency of airway, support cardiac and respiratory function according to symptoms. The antidote for respiratory depression is naloxone. However naloxone may not be useful in all cases of tramadol overdose as it may only partially reverse some of the other effects of tramadol and may increase the risks of seizures, although data on the latter are conflicting. In case of seizures, administer diazepam.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product should 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 of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Packages size:
Cardboard box of 10 colourless glass ampoules type I of 1 ml.

Marketing authorisation number:
Vm 54982/4009

Classification of the medicinal product in terms of dispensing.
For animal treatment only.
Veterinary medicinal product requiring a single-copy, non-repeatable prescription.

Approved 31 October 2022