ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Tramadol (as hydrochloride) 43.9 mg
Equivalent to 50 mg of tramadol hydrochloride

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 x 1 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTES OF ADMINISTRATION

Intramuscular or 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 opened use immediately.

11. SPECIAL STORAGE CONDITIONS

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

Dispose of waste material in accordance with local requirements.

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

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4225

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

AMPOULES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramvetol 50 mg/ml solution for injection for dogs 

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Tramadoli hydrochloridum 50 mg (equivalent to 43.9 mg tramadol)

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

1 ml

4. ROUTE(S) OF ADMINISTRATION

IM/IV

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Ad us. vet./For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Tramvetol 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:
VIRBAC - 1ère avenue 2065m LID - 06516 Carros - France

Manufacturer responsible for batch release:
Labiana Life Sciences S.A. - Venus 26 - 08228 Terrassa (Barcelona) - Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:
Active substance:
Tramadol hydrochloride 50 mg (equivalent to 43.9 mg tramadol)
Clear and colourless solution, free from visible particles.

4. INDICATION

For the reduction of mild postoperative pain.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to 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 this product. In rare cases hypersensitivity can occur. In cases of hypersensitivity reactions the treatment should be discontinued.
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).

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.

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

7. TARGET SPECIES

Dogs.

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

For intramuscular or intravenous use: 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

Intravenous administration must be carried out very slowly.

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This 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 and ampoule after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: immediate use.

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 invidual 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. For chronic pain, multimodal analgesia should be considered. Dogs should be monitored regulary by a veterinarian to ensure adequate

pain relief. In the case of recurrence of pain or insufficient analgesia the analgesic protocol may need to be reconsidered.

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 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.
This 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.
This product 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.
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, lactation and fertility:
In laboratory studies conducted on mice and / or rats and rabbits respectively, the use of tramadol:
- did not reveal the existence of teratogenic, foetotoxic, maternotoxic effects, in case of pregnancy,
- did not show any adverse effects in the peri and post-natal period of offspring, in case of lactation,
- at therapeutic doses, did not induce the appearance of unfavourable reactions on reproductive parameters and fertility in the male and female.

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 this product with central nervous system depressants system may potentiate the effects on C.N.S. and respiratory depressant effects.
When the product is administered together with medicinal products with a sedative effect, the duration of sedation may be increased.
This product can induce seizures and increase the effect of drugs that lower the convulsive 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. 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 section “Contraindications”

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 includes, in particular, miosis, vomiting, cardiocirculatory collapse, disturbances of consciousness up to coma, convulsions and respiratory depression up to the 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

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

Medicines should not be disposed of in wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2024

15. OTHER INFORMATION

Pack size: box containing 10 ampoules.

Approved 28 April 2024