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 tablets for dogs
tramadol hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains:

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

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

30 tablets
100 tablets

5. TARGET SPECIES

Dogs weighing more than 6.25 kg.

6. INDICATION(S)

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}
Shelf life of divided tablets: 3 days

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 05653/4224

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramvetol 50 mg tablets for dogs weighing more than 6.25 kg.  >
6.25 kg
Tramadoli hydrochloridum/Tramadol hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Ad us.vet./For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Tramvetol 50 mg tablets 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 Pharmaceuticals S.L.U. - C/ Casanova - 27-31 08757 Corbera del Llobregat - Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramvetol 50 mg tablets for dogs
tramadol hydrochloride

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

One tablet contains:
Active substances:
Tramadol (as hydrochloride) 43.9 mg
Equivalent to 50 mg of tramadol hydrochloride

White to almost white tablets with brown dots with a break line on one side, flat, with rounded edges and a characteristic smell of meat.
Tablets can be divided into 2 equal parts.

4. INDICATION(S)

For the reduction of acute and chronic mild soft tissue and musculoskeletal pain.

5. CONTRAINDICATIONS

Do not administer in conjunction with tricyclic antidepressants, monoamine oxidase inhibitors and serotonin reuptake inhibitors.
Do not use in cases of hypersensitivity to tramadol or to any of the excipients.
Do not use in animals with epilepsy.

6. ADVERSE REACTIONS

Mild sedation and drowsiness may commonly occur, especially when higher doses are given.
Nausea and vomiting have uncommonly been observed in dogs after administration of tramadol.
In rare cases hypersensitivity can occur. In cases of hypersensitivity reactions the treatment should be discontinued.
In very rare cases this product may induce convulsions in dogs with a low seizure threshold.

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

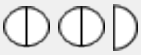
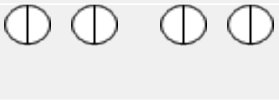
Dogs weighing more than 6.25 kg

 > 6.25 kg

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

For oral use.
The recommended dose is 2-4 mg tramadol hydrochloride per kg body weight every 8 hours or as needed based on the intensity of pain.
Minimum dosing interval is 6 hours. The recommended maximum daily dose is 16 mg/kg. 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. The dog should be examined regularly by a veterinarian to assess if additional analgesia is subsequently required. Additional analgesia can be administered by increasing the tramadol dose until the maximum daily dose is reached, and/or by following a multimodal analgesic approach with the addition of other suitable analgesics.

Please note that this dosing table is intended as a guide for dispensing the product at the high end of the dose range: 4 mg/kg bodyweight. It states the number of tablets required to administer 4 mg tramadol hydrochloride per kg bodyweight.

4 mg / kg bodyweight	No Tablets Tramadol 50 mg
< 6.25 kg	NA
6.25 kg	½ 
12.5 kg	1 
18.75 kg	1 + ½ 
25 kg	2 
31.25 kg	2 + ½ 
37.5 kg	3 
50 kg	4 
62.5 kg	5 

9. ADVICE ON CORRECT ADMINISTRATION

Tablets can be divided into 2 equal parts to ensure accurate dosing.

To divide the tablet, take it with its scored side facing up and press down with your thumbs on both sides of the tablet.

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 and blister after EXP. The expiry date refers to the last day of that month.

Shelf life of divided tablets: 3 days

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. For chronic pain, multimodal analgesia should be considered. Dogs should be monitored regularly by a veterinarian to ensure adequate pain relief. In 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 this product 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. Cessation of long-term analgesic therapy should be done gradually whenever possible.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product may cause sedation, nausea and dizziness after accidental ingestion, especially by children. To avoid accidental ingestion, particularly by a child, unused tablet parts should be returned to the open blister space and inserted back into the carton and kept in a safe place out of the sight and reach of children.
In case of accidental ingestion, particularly by children, seek medical advice immediately and show the package leaflet or the label to the physician. In case of accidental ingestion by adults: DO NOT DRIVE as sedation may occur.
People with known hypersensitivity to tramadol or any of the excipients should avoid contact with the veterinary medicinal product.
Wash hands after use.

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.
- did not show any negative effects in the peri and post-natal period of the offspring.
- 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 depressant drugs of the central nervous system may potentiate the effects on C.N.S. and respiratory depressant effects.

This product can 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 this product. The clinical relevance of this interaction has not yet been definitively studied. The combination with mixed agonist/antagonists (e.g. buprenorphine, butorphanol) and the product is not advisable, because the analgesic effect of a pure agonist may be theoretically reduced in such circumstances. See also 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. These 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. Inducing vomiting in order to empty the stomach is suitable unless the affected animal is showing reduced consciousness, in which case gastric lavage may be considered. 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. In case of seizures, administer diazepam.

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.
Medicines should not be disposed of via 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

15. OTHER INFORMATION

Pack sizes:
Box of 3 blisters of 10 tablets
Box of 10 blisters of 10 tablets

Not all pack sizes may be marketed.

Approved 21 October 2019