1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramvetol 50 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:

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

Excipients:

Qualitative composition of excipients and other constituents
Cellulose, microcrystalline
Starch, pregelatinized
Saccharin sodium
Meat flavour
Silica, colloidal anhydrous
Magnesium stearate

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs (weighing more than 6.25 kg).

3.2 Indications for use for each target species

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

3.3 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.

3.4 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. 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.

3.5 Special precautions for use

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. 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:

Tramadol 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Sedation[1], Drowsiness[1]
Uncommon (1 to 10 animals / 1 000 animals treated):	Nausea, Vomiting
Rare (1 to 10 animals / 10 000 animals treated):	Hypersensitivity reaction[2]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Convulsion[3]

[1]Mild, especially when higher doses are given
[2]The treatment should be discontinued
[3]In dogs with a low seizure threshold

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Laboratory studies in mice and / or rats and rabbits, respectively, the use of tramadol 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, respectively, the use of tramadol have not produced any evidence of negative effects in the peri and post-natal period of offspring. Use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:
Laboratory studies in mice and / or rats and rabbits respectively, the use of tramadol at therapeutic doses did not induce the appearance of unfavorable reactions on reproductive parameters and fertility in the male and female. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

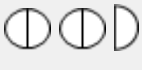
Concomitant administration of this veterinary medicinal product with depressant drugs of the central nervous system may potentiate the effects on C.N.S and respiratory depressant effects.

This veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product is not advisable, because the analgesic effect of a pure agonist may be theoretically reduced in such circumstances. See also section 3.3.

3.9 Administration routes and dosage

For oral use.
The recommended dose is 2-4 mg tramadol hydrochloride per kg bodyweight 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 tramadol hydrochloride per kg bodyweight. 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 veterinary medicinal product at the high end of the dose range: 4 mg tramadol hydrochloride per 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	

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN02AX02

4.2 Pharmacodynamics

Tramadol is a centrally acting analgesic agent with a complex mode of action exerted by its 2 enantiomers and primary metabolite, involving opioid, norepinephrine, and serotonin receptors. The (+) enantiomer of tramadol has a low affinity for the μ-opioid receptors, inhibits serotonin uptake and enhances its release. The (-) enantiomer preferentially inhibits norepinephrine reuptake. The metabolite O-desmethyltramadol (M1) has greater affinity for the μ-opioid receptors. Unlike morphine, tramadol does not have depressing effects on respiration for an extensive analgesic dose range. Likewise, it does not affect gastrointestinal motility. The effects on the cardiovascular system tend to be mild. The analgesic potency of tramadol is about 1/10 to 1/6 of that of morphine.

4.3 Pharmacokinetics

Tramadol is readily absorbed: After a single oral administration of 4.4 mg tramadol hydrochloride per kg bodyweight, peak plasma concentrations of 65 ng tramadol per mL are achieved within 45 minutes. Food does not significantly affect the absorption of the drug.

Tramadol is metabolized in the liver by cytochrome P450 mediated demethylation followed by conjugation with glucuronic acid. In dogs, lower levels of the active metabolite O-desmethyltramadol are formed compared to humans. Elimination occurs mainly via the kidneys with an elimination half-life of about 0.5-2 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life of divided tablets: 3 days

5.3. Special precautions for storage

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

5.4 Nature and composition of immediate packaging

White PVC/PE/PVDC - aluminium blister.

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

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

VPA10988/111/001

8. DATE OF FIRST AUTHORISATION

30/08/2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

26/01/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).