1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRAMADOG 50 mg tablet for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Tramadol base .....43.90 mg
(equivalent to 50.00 mg tramadol hydrochloride)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
White to cream slightly spotted, round and convex tablet of 10 mm with a cross-shaped break mark.
The tablets can be divided into 2 or 4 equal parts.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals

As tablets are flavoured, store tablets out of reach of the animals in order to avoid accidental ingestion.
The tablet can only be dosed correctly in dogs weighing more than 3.12 kg.
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. 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.

4.6 Adverse reactions (frequency and seriousness)

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 tramadol 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).

4.7 Use during pregnancy, lactation or lay

Pregnancy:
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. Use only according to the benefit-risk assessment by the responsible veterinarian.

Lactation:
In laboratory studies conducted on mice and / or rats and rabbits, respectively, the use of tramadol did not show any negative effects in the peri and post-natal period of offspring. Use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:
In laboratory studies conducted on mice and / or rats and rabbits respectively, the use of tramadol 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.

4.8 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 4.3 Contraindications.

4.9 Amounts to be administered and administration route

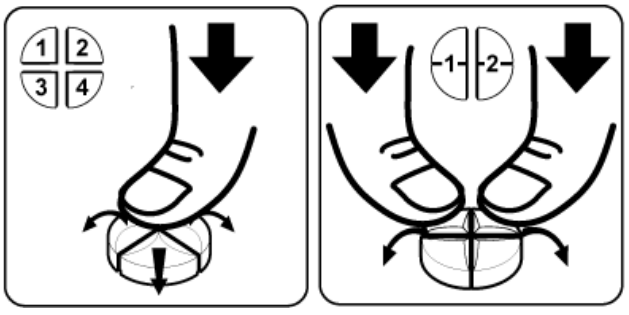
For oral use.

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 animal, 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.

Dog bodyweight	4 mg/kg dosage and no. of product tablets per administration		
3.12 kg	12.5 mg	1/4	
6.25 kg	25 mg	1/2	
9.37 kg	37.5 mg	3/4	
12.5 kg	50 mg	1	
15.62 kg	62.5 mg	1+ 1/4	
18.75 kg	75 mg	1 + 1/2	
21.87 kg	87.5 mg	1 + 3/4	
25 kg	100 mg	2	
> 25 kg	administer an additional ¼ tablet ( ) per 3.12 kg bodyweight in excess of 25 kg		

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



4 equal parts: press down with your thumb in the middle of the tablet.
2 equal parts: press down with your thumbs on both sides of the tablet.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Analgesics, other opioids, tramadol
ATCvet-code: QN02AX02

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

Tramadol is readily absorbed: after a single oral administration of 4.2 mg tramadol HCL per kg bodyweight peak plasma concentrations of 18.49 ng tramadol per mL are achieved within about 1 hour. 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 approximately 45 minutes.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose, microcrystalline
Starch, pregelatinised
Beef flavour
Saccharin sodium
Silica, colloidal anhydrous
Magnesium stearate
Masking flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4. Special precautions for storage

After piercing a blister, replace unused tablet parts into the blister and place the blister back into the cardboard box.

This medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

PVC-PVDC / aluminium thermosealed blister containing 10 tablets.

Box of 1 blister (10 tablets).
Box of 3 blisters (30 tablets).
Box of 6 blisters (60 tablets).
Box of 10 blisters (100 tablets).

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

AXIENCE

8. MARKETING AUTHORISATION NUMBER(S)

VPA22873/006/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/07/2022

10 DATE OF REVISION OF THE TEXT

18/07/2025

PROHIBITION OF SALE, SUPPLY AND/OR USE