SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramcoat 8 mg film-coated tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Tramadol hydrochloride 8 mg
equivalent to 7.0 mg tramadol

Excipients:

Qualitative composition of excipients and other constituents
Tablet Core
Cellulose, microcrystalline
Saccharin sodium
Vanillin
Lactose monohydrate
Sodium starch glycolate (type A)
Magnesium stearate
Silica, colloidal hydrated
Tablet Coating
Titanium dioxide
Polyvinyl alcohol
Talc
Glycerol monocaprylocaprate
Sodium laurilsulfate
Pigment: Pink: Iron oxide black, Iron oxide red

Pink film-coated tablet with a modified ball shape (size 4 mm).

3. CLINICAL INFORMATION

3.1 Target species

Dogs

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 the active substance 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:
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of 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 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. To avoid accidental ingestion, particularly by children, blisters should be 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 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.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Frequency	Adverse event
Common (1 to 10 animals / 100 animals treated):	Sedation[1,2]; drowsiness – neurological disorder[2]
Uncommon (1 to 10 animals / 1000 animals treated):	Nausea; vomiting

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Convulsion[4]

[1] Mild.
[2] Especially when higher doses are given.
[3] In cases of hypersensitivity reactions the treatment should be discontinued.
[4] 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 and lactation:
Laboratory studies in mice and/or rats and rabbits have not produced any evidence of teratogenic, foetotoxic, maternotoxic effects and 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.

3.8 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 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 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 3.3 Contraindications.

3.9 Administration routes and dosage

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.
The minimum dosing interval is 6 hours. The recommended maximum total daily dose is 16 mg/kg. As the individual response to tramadol is variable and partly depends 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/kg bodyweight. It states the number and type of tablets required to administer 4 mg tramadol hydrochloride per kg bodyweight per administration.

The recommended dose is 2-4 mg tramadol HCl per kg. In this table an example of 4 mg tramadol HCl per kg is stated.

Body weight	Veterinary medicinal product			
	8 mg	20 mg	40 mg	80 mg
2 kg	●			
4 kg	● ●			
5 kg		●		
7 kg	● +	●		
10 kg			●	
20 kg				●
30 kg			● +	●
40 kg				● ●
50 kg			● +	● ●
60 kg				● ● ●

A suitable combination of tablet sizes should be used in order to administer the optimal dosage for each dog. To ensure a correct dosage, body weight should be determined as accurately as possible.

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 152 ng tramadol per mL are achieved within 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 about 50 minutes.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 27 months.

5.3 Special precautions for storage

Do not store above 30°C.

5.4 Nature and composition of immediate packaging

PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.
Cardboard box of 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120 or 250 tablets.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

7. MARKETING AUTHORISATION NUMBER

Vm 36408/3032

8. DATE OF FIRST AUTHORISATION

13 March 2024

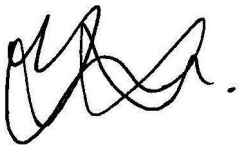
9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

March 2024

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).



Approved: 13 March 2024