

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

{Outer carton}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

TRAMADOG 50 mg tablet for dogs  
Tramadol hydrochloride

**2. STATEMENT OF ACTIVE SUBSTANCES**

43.90 mg tramadol base (equivalent to 50.00 mg of tramadol hydrochloride)

**3. PHARMACEUTICAL FORM**

Tablet

**4. PACKAGE SIZE**

10 tablets  
30 tablets  
60 tablets  
100 tablets



**5. TARGET SPECIES**

Dogs



**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Oral use.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

**9. SPECIAL WARNING(S), IF NECESSARY**

**Accidental ingestion of this product may be harmful.** 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.  
Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

**11. SPECIAL STORAGE CONDITIONS**

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

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

Disposal: read package leaflet

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only - *to be completed during the national phase.*

**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**

Domes Pharma  
3 Rue André Citroën  
63430 Pont-Du-Chateau  
France

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 54982/4002

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

{Blister}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

TRAMADOG 50 mg tablet for dogs  
Tramadoli hydrochloridum/Tramadol hydrochloride



**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

DOMES PHARMA

**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:**  
TRAMADOG 50 mg tablet 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 :

Domes Pharma  
3 Rue André Citroën  
63430 Pont-Du-Chateau  
France

Manufacturer responsible for batch release:

EUROPHARTECH  
34 rue Henri Matisse – BP 23  
63370 LEMPDES  
FRANCE

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

TRAMADOG 50 mg tablet for dogs

Tramadol hydrochloride

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

Each tablet contains:

**Active substance:**

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

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. 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 known cases of hypersensitivity to the active substance 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 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).

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 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.

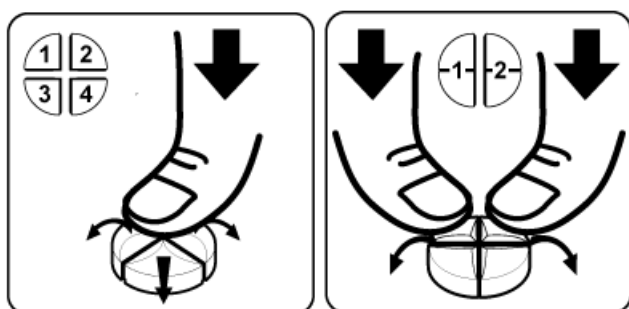
Dog bodyweight 	4 mg/kg dosage and no. of product tablets per administration		
3.12 kg	12.5 mg	1/4	
6.25 kg	25 mg	1/2	
9.37 kg	37.5 mg	3/4	
12.5 kg	50 mg	1	
15.62 kg	62.5 mg	1 + 1/4	



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 1/4 tablet (  ) per 3.12 kg bodyweight in excess of 25 kg		

**9. ADVICE ON CORRECT ADMINISTRATION**

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.

**10. WITHDRAWAL PERIOD(S)**

Not applicable.

**11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after "EXP". The expiry date refers to the last day of that month.

**12. SPECIAL WARNING(S)**

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.

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 offspring.
- 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.

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 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**

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon 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**

Package sizes:

Cardboard box of 10 tablets

Cardboard box of 30 tablets

Cardboard box of 60 tablets

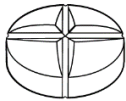
Cardboard box of 100 tablets

Not all pack sizes may be marketed.

Marketing Authorization Number:

Classification of the medicinal product in terms of dispensing:

*To be completed at the national phase.*



Divisible tablet.

Approved: 01 March 2022