I. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET
Induction sealed polypropylene containers with child-resistant polypropylene closures.

Packaging consists of one concertina label made up of a peel back outer label, a packaging leaflet, and an inner, immediate label in contact with the bottle. For the purposes of the QRD template these components have been listed separately.

PARTICULARS TO APPEAR ON OUTER LABEL

1 NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation holder: Drug Development Company Limited, 2nd Floor Godfree Court, Apex Yard, 29 Long Lane, London SE1 4PL

2 NAME OF THE VETERINARY MEDICINAL PRODUCT

TRAMALGESIC 50 mg tablets for dogs
tramadol hydrochloride 50 mg equivalent to 43.9 mg tramadol base

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

tramadol hydrochloride 50 mg

4 PHARMACEUTICAL FORM

Tablet

5 PACKAGE SIZE

56 tablets
200 tablets

6 INDICATION(S)

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

9 TARGET SPECIES

Dogs.

10 METHOD AND ROUTES OF ADMINISTRATION

For oral administration.

12 WITHDRAWAL PERIOD(S)

13 SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Store in the original container

14 SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use
Accidental ingestion of this product may be harmful, especially to children.

15 EXPIRY DATE

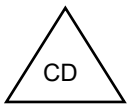
EXP:

16 SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18 THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V



(Sch 3)

For animal treatment only.
Dispense in child resistant containers.
To be supplied only on veterinary prescription.

19 WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

20 MARKETING AUTHORISATION NUMBER(S)

Vm 50554/4000

21. MANUFACTURER'S BATCH NUMBER

Lot:

22 OTHER INFORMATION

Peel here to open.

PARTICULARS TO APPEAR ON IMMEDIATE LABEL

1 NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Drug Development Company Limited, 2nd Floor Godfree Court, Apex Yard, 29 Long Lane, London SE1 4PL, United Kingdom

2 NAME OF THE VETERINARY MEDICINAL PRODUCT

TRAMALGESIC 50 mg tablets for dogs
tramadol hydrochloride 50 mg equivalent to 43.9 mg tramadol base

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

tramadol hydrochloride 50 mg

4 PHARMACEUTICAL FORM

Tablet

5 PACKAGE SIZE

56 tablets
200 tablets

6 INDICATION(S)

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

9 TARGET SPECIES

Dogs.

10 METHOD AND ROUTES OF ADMINISTRATION

For oral administration.

12 WITHDRAWAL PERIOD(S)

13 SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Store in the original container

14 SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use

Accidental ingestion of this product may be harmful, especially to children.

15 EXPIRY DATE

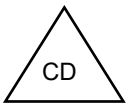
EXP:

16 SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18 WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V



(Sch 3)

For animal treatment only.
Dispense in child resistant containers.
To be supplied only on veterinary prescription.

19 THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

20 MARKETING AUTHORISATION NUMBER(S)

Vm 50554/4000

21 MANUFACTURER'S BATCH NUMBER

Lot No:

PARTICULARS TO APPEAR IN THE PACKAGE LEAFLET

Please also refer to "PARTICULARS TO APPEAR ON THE OUTER LABEL" as this forms the first page of the package leaflet.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation holder:
Drug Development Company Limited
2nd Floor Godfree Court
Apex Yard, 29 Long Lane
London
SE1 4PL

Manufacturer responsible for batch release:
Custom Pharmaceuticals Limited
Conway Street, Hove
East Sussex, BN3 3LW
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRAMALGESIC 50 mg tablets for dogs
tramadol hydrochloride

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

1 tablet contains

Active substance:
Tramadol hydrochloride 50 mg equivalent to 43.9 mg tramadol base.

Brown-beige-white mottled round, flat beveled edge tablets. Embossed 'TV50' on one face with a quadrisect break line on reverse.

Tablets can be divided into 2 or 4 equal parts.

4. PHARMACEUTICAL FORM

Tablets

5. PACKAGE SIZE

56 tablets
200 tablets

6. INDICATION(S)

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

7. CONTRAINDICATIONS

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

8. 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, 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 if you think that the medicine has not worked, please inform your veterinary surgeon.

9. TARGET SPECIES

Dogs.

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHODS OF ADMINISTRATION

For oral administration.
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.

11. 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.

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

12. WITHDRAWAL PERIOD(S)

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Store in the original container to protect from moisture.
Half or quarter tablets should be replaced back into the original container and should be given at the next administration.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
The expiry date refers to the last day of that month.

14. SPECIAL WARNINGS <USER WARNINGS>

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 veterinary surgeon 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 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
Accidental ingestion of this product may be harmful, especially to children. Tramadol may cause sedation, nausea and dizziness.
If smaller quantities of tablets are dispensed from the pack, they must be supplied in a container with a child-resistant closure.

To avoid accidental ingestion by a child, the cap of the container must be securely engaged at all times. Tablets to be administered must not be left unattended and unused part tablets should be returned to the container.
In case of accidental ingestion, particularly by children, seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive as sedation may occur.
People with known hypersensitivity to tramadol should avoid contact with the veterinary medicinal product.
Wash hands after use.

Use during pregnancy and lactation
Pregnancy:
Laboratory studies conducted in mice and/or rats and rabbits have not produced any evidence of teratogenic, foetotoxic, maternotoxic effects. Use only in accordance with the risk-benefit assessment of the responsible veterinary surgeon.

Lactation:
Laboratory studies in mice and/or rats and rabbits have not produced any evidence of negative effects on the peri- and post-natal development of offspring. Use only in accordance with the risk-benefit assessment of the responsible veterinary surgeon.

Fertility:
In laboratory studies in mice and/or rats and rabbits, the use of tramadol at therapeutic doses did not adversely affect reproductive and fertility parameters in males and females. Use only in accordance with the risk-benefit assessment of the responsible veterinary surgeon.

Interactions with other medicinal products and other forms of interaction

Concomitant administration of the 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 4.3.

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.

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS, IF ANY

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

17. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<To be inserted>

22. OTHER INFORMATION

Induction sealed polypropylene containers with child-resistant polypropylene closures.
Pack sizes of 56 or 200 divisible tablets per container.
Not all pack sizes may be marketed.

Logo – PDSA Vet Care

Approved 21 January 2022