ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramatab 120 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Tramadol (as hydrochloride) 105.4 mg/tablet

3. PACKAGE SIZES

10 tablets
30 tablets
50 tablets
100 tablets

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTE(S) OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIOD(S)

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Accidental ingestion of this veterinary medicinal product can be harmful. Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

CP Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

Vm 20916/3014

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramatab

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Tramadol (as hydrochloride) 105.4 mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Tramatab 120 mg chewable tablets for dogs

2. Composition

Each tablet contains:

Active substance:

Tramadol (as hydrochloride) 105.4 mg
Equivalent to 120 mg of tramadol hydrochloride

Light brown with brown spots, round and convex tablet with a cross-shaped break line on one side. The tablet can be divided into equal halves and quarters.

3. Target species

Dogs

4. Indication(s) for use

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 cases of hypersensitivity to tramadol or to any of the excipients.
Do not use in animals with epilepsy.

6. Special warning(s)

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.

Special precautions for safe use in the target species:
As tablets are flavoured, store tablets out of reach of animals in order to avoid accidental ingestion.
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 hypersensitivity reactions. People with known hypersensitivity to tramadol should avoid contact with the veterinary medicinal product. Wash hands after use. Seek medical advice in case of hypersensitivity reactions.

Tramadol may cause eye irritation, e.g., if dust is formed when the tablets are broken into smaller parts. Avoid contact with the eyes, including hand-to-eye contact. If the veterinary medicinal product comes into contact with the eyes, rinse immediately with plenty of water.
Tramadol may cause sedation, nausea and dizziness after accidental ingestion. 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.

Pregnancy and lactation:
Laboratory studies in mice and/ or rats and rabbits have not produced any evidence of teratogenic, foetotoxic, maternotoxic effects nor adverse effects in the peri- and postnatal development of offspring.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:
Laboratory studies in mice and/ or rats and rabbits, with 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.

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.

Overdose:
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.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Sedation[1,2], Drowsiness - neurological disorder[2]
Uncommon (1 to 10 animals / 1,000 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. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder, using the contact details at the end of this leaflet, or via your national reporting system <{national system details}.

8. Dosage for each species, routes and method of administration

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 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

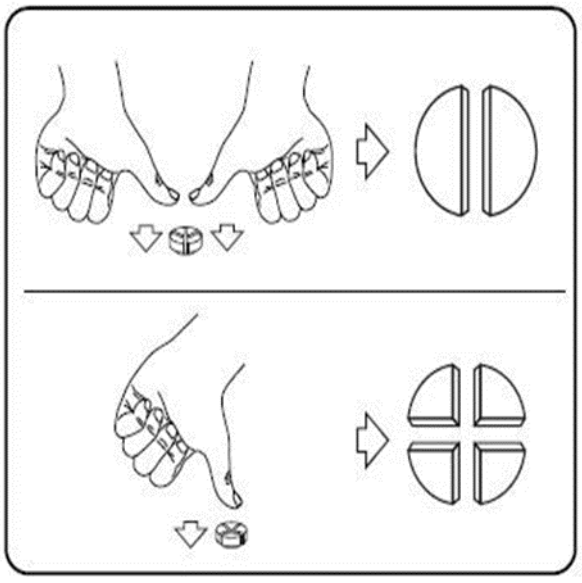
of other suitable analgesics.
The most appropriate tablet strengths should be used in order to provide accurate dose rates and minimise divided tablets to be kept until the next dosing. The remaining tablet fraction(s) should be used in the next administration(s).

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 per administration. The recommended dose is 2-4 mg tramadol hydrochloride per kg body weight. This table gives an example of 4 mg tramadol hydrochloride per kg BW.

Body weight (kg)	Number of 120 mg tablets
30	1
45	1½
60	2
75	2½
90	3

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
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.



Halves: press down with your thumbs on both sides of the tablet.
Quarters: press down with your thumb in the middle of the tablet.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary 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 carton and the blister after Exp. The expiry date refers to the last day of that month.

12. Special precautions for the disposal

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 applicable national collection systems.
These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation and pack sizes

Vm 20916/3014

Aluminium-PVC/Aluminium/oPA blisters, containing 10 tablets.

Cardboard box of 10 tablets
Cardboard box of 30 tablets
Cardboard box of 50 tablets
Cardboard box of 100 tablets

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany
<only in case marketing authorisation holder is also the local contact to report suspected adverse reactions: Tel: +49 (0)5136 60660>

Local representatives and contact details to report suspected adverse reactions:

United Kingdom (Northern Ireland)
DUGV (UK) Ltd.,
Union House, 111 New Union Street,
Coventry, CV1 2NT, United Kingdom
T: 02476 100696
E: uksales@dugganvet.com

17. Other information

Gavin Hall
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