ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxitab 1 mg tablets for dogs
Loxitab 2.5 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:

Active substance:

Meloxicam	1 mg
Meloxicam	2.5 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Cellulose, microcrystalline
Sodium citrate dihydrate
Crospovidone
Silica, colloidal hydrated
Magnesium stearate
Chicken flavour
Yeast (dried)

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

3.3 Contraindications

Do not use in pregnant or lactating animals.
Do not use in dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in dogs less than 6 weeks of age or less than 2 kg body weight.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, a meloxicam 0.5 mg/ml oral suspension for cats should be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAID's) or to any of the excipients should avoid contact with the veterinary medicinal product.
Accidental ingestion, especially by children, may cause adverse reactions. Unused tablet parts should be placed back into the blister and carton and carefully kept away from children. In case of accidental ingestion by a child seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

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

3.6 Adverse events

Dogs:

Very rare **(<1 animal / 10,000 animals treated, including isolated reports):**	Vomiting Diarrhoea Blood in faeces* Haemorrhagic diarrhoea Haematemesis Gastric ulceration Renal failure Lethargy Appetite loss Elevated liver enzymes

*faecal occult blood

These side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section 3.3).

3.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Loxitab must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacological properties of the products used previously.

3.9 Administration routes and dosage

Oral use.

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day, which can be given orally or alternatively using meloxicam 5 mg/ml solution for injection for dogs.

Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight.
Each tablet contains either 1 mg or 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 10 kg body weight dog, or a 25 kg body weight dog respectively.

Each tablet can be halved or quartered for accurate dosing according to the individual body weight of the dog. Loxitab tablets are flavoured and can be administered with or without food.

Dose scheme for the maintenance dose:

Body weight (kg)	Number of tablets		mg/kg
	1 mg	2.5 mg	
2.0 – 3.5	¼		0.07 - 0.13
3.6 – 6.0	½		0.08 - 0.14
6.1 – 8.0	¾		0.09 - 0.12
8.1 – 10.0	1		0.10 - 0.12
10.1 – 12.5	1¼		0.10 - 0.12
12.6 – 15.0	1½		0.10 - 0.12
15.1 – 17.5	1¾		0.10 - 0.12
17.6 – 20.0	2		0.10 - 0.11
20.1 – 25.0		1	0.10 - 0.12
25.1 – 30.0		1¼	0.10 - 0.12
30.1 – 35.0		1½	0.11 - 0.12
35.1 – 40.0		1¾	0.11 - 0.12
40.1 – 45.0		2	0.11 - 0.12
45.1 – 50.0		2¼	0.11 - 0.12

A clinical response is normally seen within 3–4 days. Treatment should be discontinued after 10 days if no clinical improvement is apparent.

The remaining tablet portion should be given at the next administration.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose symptomatic treatment should be initiated.

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: QM01AC06

4.2 Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

4.3 Pharmacokinetics

Absorption
Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 4.5 hours. When the product is used according to the recommended dosage regime, steady state concentrations of meloxicam in plasma are reached on the second day of treatment.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range. Approximately 97% of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg.

Metabolism
Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a half-life of 24 hours. Approximately 75% of the administered dose is eliminated in faeces and the remainder in urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

PVC/PE/PVDC (white)-Alu blister, containing 10 tablets each.

Pack sizes:
Cardboard box containing 10 tablets
Cardboard box containing 30 tablets
Cardboard box containing 50 tablets
Cardboard box containing 100 tablets

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

CP- Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/23/301/0001-008

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 19/10/2023

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

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).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box /1 mg strength

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxitab 1 mg tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 1 mg

3. PACKAGE SIZE

10 tablets
30 tablets
50 tablets
100 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

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 CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

CP- Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/23/301/001 (10 tablets)
EU/2/23/301/002 (30 tablets)
EU/2/23/301/003 (50 tablets)
EU/2/23/301/004 (100 tablets)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister (PVC/PE/PVDC-Alu)/ 1 mg strength

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxitab

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 1 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box /2.5 mg strength

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxitab 2.5 mg tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 2.5 mg

3. PACKAGE SIZE

10 tablets
30 tablets
50 tablets
100 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

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 CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

CP- Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/23/301/005 (10 tablets)
EU/2/23/301/006 (30 tablets)
EU/2/23/301/007 (50 tablets)
EU/2/23/301/008 (100 tablets)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister (PVC/PE/PVDC-Alu)/2.5 mg strength

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxitab

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 2.5 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Loxitab 1 mg tablets for dogs
Loxitab 2.5 mg tablets for dogs
Meloxicam

2. Composition

One tablet contains:
Meloxicam 1 mg
Meloxicam 2.5 mg

Light brown with brown spots, round 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. Indications for use

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

5. Contraindications

Do not use in pregnant or lactating animals.
Do not use in dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in dogs less than 6 weeks of age or less than 2 kg body weight.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.
This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, a meloxicam 0.5 mg/ml oral suspension for cats should be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to non-steroidal anti-inflammatory drugs NSAID's or to any of the excipients should avoid contact with the veterinary medicinal product.
Accidental ingestion, especially by children, may cause adverse reactions. Unused tablet parts should be placed back into the blister and carton and carefully kept away from children. In case of accidental ingestion by a child, seek medical advice immediately and show this package leaflet or the carton to the physician.
Wash hands after use.

Pregnancy and lactation:
See section “Contraindications”.

Interaction with other medicinal products and other forms of interaction:
Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Loxitab must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacological properties of the products used previously.

Overdose:
In case of overdose symptomatic treatment should be initiated.

7. Adverse events

Dogs:

Very rare **(<1 animal / 10,000 animals treated, including isolated reports):**	Vomiting Diarrhoea Blood in faeces* Haemorrhagic diarrhoea Haematemesis Gastric ulceration Renal failure Lethargy Appetite loss Elevated liver enzymes

*faecal occult blood

These side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a 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.

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day, which can be given orally or alternatively using meloxicam 5 mg/ml solution for injection for dogs.

Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight.

Each tablet contains either 1 mg or 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 10 kg body weight dog, or a 25 kg body weight dog respectively.
Each tablet can be halved or quartered for accurate dosing according to the individual body weight of the dog. Loxitab tablets are flavoured and can be administered with or without food.

Dose scheme for the maintenance dose:

Body weight (kg)	Number of tablets		mg/kg
	1 mg	2.5 mg	
2.0 – 3.5	¼		0.07 - 0.13
3.6 – 6.0	½		0.08 - 0.14
6.1 – 8.0	¾		0.09 - 0.12
8.1 – 10.0	1		0.10 - 0.12
10.1 – 12.5	1¼		0.10 - 0.12
12.6 – 15.0	1½		0.10 - 0.12
15.1 – 17.5	1¾		0.10 - 0.12
17.6 – 20.0	2		0.10 - 0.11
20.1 – 25.0		1	0.10 - 0.12
25.1 – 30.0		1¼	0.10 - 0.12
30.1 – 35.0		1½	0.11 - 0.12
35.1 – 40.0		1¾	0.11 - 0.12
40.1 – 45.0		2	0.11 - 0.12
45.1 – 50.0		2¼	0.11 - 0.12

A clinical response is normally seen within 3–4 days. Treatment should be discontinued after 10 days if no clinical improvement is apparent.

9. Advice on correct administration

Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian.
Instructions for opening the blisters: Push the tablet for release from the blister.

The remaining tablet portion should be given at the next administration.

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.

12. Special precautions for 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 numbers and pack sizes

EU/2/23/301/0001-008

Loxitab 1 mg and 2.5 mg tablets for dogs.

PVC/PE/PVDC (white)-Alu blister, containing 10 tablets each.

Pack sizes:
Cardboard box containing 10 tablets
Cardboard box containing 30 tablets
Cardboard box containing 50 tablets
Cardboard box containing 100 tablets

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

CP- Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
CP- Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Duitsland/ Allemagne/ Deutschland/
Tel: +49 (0)5136 60660

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Zoovetvaru OÜ
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