PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box of blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lemicam 2.5 mg chewable tablets for dogs
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 2.5 mg/chewable tablet

3. PHARMACEUTICAL FORM

Chewable tablets

4. PACKAGE SIZES

7 tablets
84 tablets
252 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Lemicam 2.5 mg chewable tablets for dogs:
Oral use.
Single dose on the first day: 0.2 mg meloxicam/kg body weight. Maintenance dose: 0.1 mg meloxicam/kg body weight once daily (1 chewable tablet per 25 kg body weight).

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.
Unused tablet halves should be stored in the blister and given at the next administration.

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

Disposal: read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE,

For animal treatment only. To be supplied only on veterinary prescription. POM-V

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

Felix Pharmaceuticals PVT Limited
25-28 North Wall Quay
Dublin 1
D01H104
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 53540/5001

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lemicam 2.5 mg chewable tablets for dogs

Meloxicam

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Felix Pharmaceuticals Pvt. Ltd., Ireland

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

A. PACKAGE LEAFLET

PACKAGE LEAFLET:
Lemicam 1 mg chewable tablets for dogs
Lemicam 2.5 mg chewable tablets 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:
Felix Pharmaceuticals PVT Limited
25-28 North Wall Quay
Dublin 1
D01H104
Ireland

Manufacturer responsible for batch release:
Wasdell Europe Limited
IDA Science and Technology Park, Mullagharlin
Dundalk, Co. Louth, A91 DET0, Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lemicam 1 mg chewable tablets for dogs
Lemicam 2.5 mg chewable tablets for dogs
Meloxicam

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

Each tablet contains:
Meloxicam 1 mg
Meloxicam 2.5 mg

1mg: Light brown to brown coloured round mottled biconvex tablet debossed with "F and 6" on either side of breakline on one side and "M1" on other side. The tablet can be divided into halves.
2.5mg: Light brown to brown coloured round mottled biconvex tablet debossed with "F and 6" on either side of breakline on one side and "M2" on other side. The tablet can be divided into halves.

4. INDICATION(S)

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 4 kg body weight.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Typical adverse reactions of non-steroidal anti-inflammatory drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have very rarely been reported from post-marketing safety experience.
Very rare cases of haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported from post-marketing safety experience.

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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 and cats.

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 chewable 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 chewable tablet can be halved for accurate dosing according to the individual body weight of the dog. Meloxicam chewable tablets can be administered with or without food, are flavoured and are taken by most dogs voluntarily.

Dose scheme for the maintenance dose:

Body weight (kg)	Number of chewable tablets		mg/kg
	1 mg	2.5 mg	
4.0–7.0	½		0.13–0.1
7.1–10.0	1		0.14–0.1
10.1– 15.0	1½		0.15–0.1
15.1–20.0	2		0.13–0.1
20.1–25.0		1	0.12–0.1
25.1–35.0		1½	0.15–0.1
35.1–50.0		2	0.14–0.1

The use of Meloxicam oral suspension for dogs may be considered for an even more precise dosing. For dogs weighing less than 4 kg the use of Meloxicam oral suspension for dogs is recommended.
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.

10. WITHDRAWAL PERIOD(S)

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.
Unused tablet halves should be stored in the blister and given at the next administration.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the blister after EXP.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
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, 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:
People with known hypersensitivity to NSAIDs should avoid contact with the product.
Accidental ingestion of the product by a child may cause gastro-intestinal effects, such as nausea and gastric pain.
Any uneaten medicated food must be disposed of immediately and the bowl washed thoroughly.
Return part-used tablets into the blister and carton.
In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the carton to the physician.

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. Meloxicam 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 (symptoms, emergency procedures, antidotes):
In case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.
Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

15. OTHER INFORMATION

Package sizes:
Lemicam 1 mg chewable tablets for dogs Blisters: 7, 84 or 252 tablets.

Lemicam 2.5 mg chewable tablets for dogs Blisters: 7, 84 or 252 tablets.

Not all pack sizes may be marketed.

Distribution category: POM-V (To be supplied only on veterinary prescription).

Approved 24 August 2022