PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton for 15 ml, 42 ml, 100 ml or 200 ml bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxaid 1.5 mg/ml Oral Suspension for Dogs
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 1.5 mg of meloxicam,

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

15 ml
42 ml
100 ml
200 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
To be administered mixed with food or directly into the mouth.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months. Use by…

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton.

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

Dispose of waste material in accordance with local requirements.

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

Distributed by:
CVS (UK) Limited
CVS House, Owen Road, DISS, Norfolk, IP22 4ER, UK

16. MARKETING AUTHORISATION NUMBER

Vm 39787/5000

17. MANUFACTURER'S BATCH NUMBER

BN{number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label for 100 ml and 200 ml bottles}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxaid 1.5 mg/ml Oral Suspension for Dogs
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 1.5 mg of meloxicam,

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

100 ml
200 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Avoid introduction of contamination during use.
To be administered mixed with food or directly into the mouth.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months.

11. SPECIAL STORAGE CONDITIONS

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

Dispose of waste material in accordance with local requirements.

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

16. MARKETING AUTHORISATION NUMBER

Vm 39787/5000

17. MANUFACTURER'S BATCH NUMBER

BN {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label for 15 ml and 42 ml bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxaid 1.5 mg/ml Oral Suspension for Dogs
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 1.5 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

15 ml
42 ml

4. ROUTE(S) OF ADMINISTRATION

Shake well before use.
To be administered mixed with food or directly into the mouth.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Meloxaid 1.5 mg/ml Oral Suspension 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
EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

Manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

Distributed by:
CVS (UK) Limited
CVS House, Owen Road, DISS, Norfolk, IP22 4ER, UK

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxaid 1.5 mg/ml Oral Suspension for Dogs
Meloxicam

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

Each ml contains: 1.5 mg of meloxicam,
5 mg of sodium benzoate.

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 animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in known cases of hypersensitivity.
Do not use in dogs less than 6 weeks of age.

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. In very rare cases haemorrhagic diarrhoea,

haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported. 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.

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 adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

Shake well before use. To be administered mixed with a small amount of food, or directly into the mouth.
Avoid introduction of contamination during use.
Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day. 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. For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time. The suspension can be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a kg-body weight scale which corresponds to the maintenance dose volume required (i.e. 0.1 mg meloxicam/kg body weight).

The following dosing table indicates what volume to administer depending on the weight of the dog:

Bodyweight (kg)	Maintenance dosage (ml)
7.5	0.5
15	1
22.5	1.5
30	2
37.5	2.5
45	3
52.5	3.5
60	4

For the first day, twice the maintenance dosage will be required.
A clinical response is normally seen within 3 to 4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

Please follow these steps:

Step 1. Before using Meloxicam for the very first time ensure that you have the bottle, circular plastic insert(1) and syringe.

Step 2(1). Place the circular plastic insert into the neck of the bottle and push down until securely in place. Once in place the insert will not need to be removed.

Step 3.
Replace the cap on the bottle and shake it well. Take off the bottle cap and attach the dosing syringe to the bottle by gently pushing the end into the hole.

Step 4.
Turn the bottle with the syringe in place upside down and slowly withdraw the plunger until the required dose is evident.

Step 5. Turn the bottle/syringe the right way up and with a twisting movement separate the syringe from the bottle.

Step 6. Push the plunger until all contents of the syringe have been dispensed onto the food.

(1) Not applicable if the circular plastic insert is already installed.

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

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

Keep out of the sight and reach of children.
Do not use after the expiry date (EXP) stated on the carton and the bottle.
When the bottle is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the carton.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal 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.
Do not leave an unattended filled syringe in the sight or reach of children.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during 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 veterinary products used previously.

Overdose (symptoms, emergency procedures, antidotes):
In the case of overdosage symptomatic treatment should be initiated.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, 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.

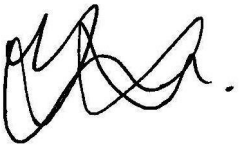
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2023

15. OTHER INFORMATION

To be supplied only on veterinary prescription.
15, 42, 100 or 200 ml bottle with two measuring syringes.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved: 27 March 2024