ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton for 125 ml or 336 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emdocam 15 mg/ml oral suspension for horses
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 15mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

125 ml
336 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTES OF ADMINISTRATION

Shake well before use.
To be administered either mixed with a small quantity of food, prior to feeding, or directly into the mouth.
After administration, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 3 days
Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating mares.

10. EXPIRY DATE

EXP <{month/year}>
Once opened, use by:
Shelf-life after first opening the container: 6 months.

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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

EMDOKA bvba
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 34534/5002

17. MANUFACTURER'S BATCH NUMBER

Lot{number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Label for bottles of 125 or 336 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emdocam 15 mg/ml oral suspension for horses
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 15mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

125 ml
336 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Read the package leaflet before use

8. WITHDRAWAL PERIOD

Meat and offal: 3 days
Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP <{month/year}>
Once opened, use by:
Shelf-life after first opening the container: 6 months.

11. SPECIAL STORAGE CONDITIONS

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

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"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

EMDOKA bvba
John Lijsenstraat 16,
B-2321 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 34534/5002

17. MANUFACTURER'S BATCH NUMBER

Lot{number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Emdocam 15 mg/ml oral suspension for horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE:

Marketing Authorisation Holder:
Emdoka bvba
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium.

Manufacturer responsible for batch release:

Produlab Pharma bv
NL-4941 SJ Raamsdonksveer
The Netherlands.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT:

Emdocam 15 mg/ml oral suspension for horses
Meloxicam

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

Each ml contains:

Active substance:
Meloxicam 15.0 mg

Excipients:
Sodium benzoate 1.5 mg

Yellow suspension.

4. INDICATIONS:

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

5. CONTRA-INDICATIONS:

Do not use in pregnant or lactating mares.
Do not use in horses suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients. Do not use in horses less than 6 weeks of age.

6. ADVERSE REACTIONS:

Isolated cases of adverse reactions typically associated with NSAIDs were observed in clinical trials (slight urticaria, diarrhoea). Symptoms were reversible.
Loss of appetite, lethargy, abdominal pain and colitis have been reported in very rare cases.
Anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically in very rare cases.

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 displaying adverse reaction(s) during the course of one treatment)
Common (more than 1 but less than 10 animals in 100 animals)
Uncommon (more than 1 but less than 10 naimals in 1,000 animals)
Rare (more than 1 but less than 10 animals in 10,000 animals)
Very rare (less than 1 animals in 10,000 animals, including isolated reports)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicines has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES:

Horses.

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

Dosage
Oral suspension to be administered at a dosage of 0.6 mg/kg body weight, once daily, up to 14 days.

Method and route of administration
Shake well before use. To be administered either mixed with a small quantity of food, prior to feeding, or directly into the mouth.
The suspension should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has volume scale and a “kg-body weight” scale which corresponds to the maintenance dose (i.e. 0.6 mg meloxicam / kg body weight).

After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

9. ADVICE ON CORRECT ADMINISTRATION:

Avoid introduction of contamination during use.

10. WITHDRAWAL PERIODS:

Meat and offal: 3 days
Not authorised for use in horses producing milk for human consumption.

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 bottle after “EXP”.

Shelf-life after first opening the container: 6 months.

12. SPECIAL WARNINGS:

Special precautions for use in animals
Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of renal toxicity.

Special precautions to be taken by the person administering the product
People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
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, lactation or lay
See section “Contraindications”.

Interactions with other medicinal products and other forms of interaction
Do not administer concurrently with glucocorticoids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

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:

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED:

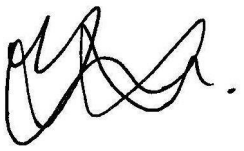
Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION:

Pack sizes:
Cardboard box with 1 bottle of 125 ml and a measuring syringe
Cardboard box with 1 bottle of 336 ml and a measuring syringe

Not all pack sizes may be marketed.

United Kingdom (Northern Ireland)
Duggan Veterinary Supplies Ltd.,
Holycross,
Thurles,
Co Tipperary
Ireland
Tel: +353 (0) 504 43169



Approved: 25 June 2021