ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> {Cardboard Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emdofluxin 50 mg/mL solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One mL contains : Flunixin (as flunixin meglumine) 50.0 mg

3. PACKAGE SIZE

50 mL
100 mL
250 mL

4. TARGET SPECIES

Horses, cattle, pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Horses: IV
Cattle: IM or IV
Pigs: IM

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal period(s):

Horses:
- Meat and offal: 10 days
- Milk: Not authorised for use in mares producing milk for human consumption.

Cattle:
- Meat and offal: 10 days (IV), 31 days (IM)
- Milk: 24 hours (IV), 36 hours (IM)

Pigs:
- Meat and offal: 20 days

8. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the immediate packaging: 28 days
Once broached, use by…

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

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

Emdoka

14. MARKETING AUTHORISATION NUMBER(S)

Vm 34534/5007

15. BATCH NUMBER

Batch {number}

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {vial of 100ml and 250ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emdofluxin 50 mg/mL solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One mL contains:

Active substance:

Flunixin (as flunixin meglumine)	50.00 mg

Excipients:

Phenol	5.00 mg
Sodium formaldehyde sulfoxylate	2.50 mg
Disodium edetate	0.10 mg

3. TARGET SPECIES

Horses, cattle, pigs

4. ROUTES OF ADMINISTRATION

Horses: IV
Cattle: IM or IV
Pigs: IM

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period(s):

Horses:
- Meat and offal: 10 days
- Milk: Not authorised for use in mares producing milk for human consumption.

Cattle:
- Meat and offal: 10 days (IV), 31 days (IM)
- Milk: 24 hours (IV), 36 hours (IM)

Pigs:
- Meat and offal: 20 days

6. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the immediate packaging: 28 days
Once broached, use by…

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka

9. BATCH NUMBER

Batch {number}

10. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

Disposal: Read package leaflet.

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

For animal treatment only.

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{50 ml vial label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emdofluxin 50 mg/mL solution for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Active substance:
Flunixin (as flunixin meglumine) 50.0 mg

3. BATCH NUMBER

Batch {number}

4. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days
Once broached, use by…

5. ROUTE(S) OF ADMINISTRATION

Horses: IV
Cattle: IM, IV
Pigs: IM

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emdofluxin 50 mg/mL solution for injection for cattle, pigs and horses

2. COMPOSITION

One mL contains:

Active substance:	
Flunixin (as flunixin meglumine)	50.0 mg
Excipients:	
Phenol	5.0 mg
Sodium formaldehyde sulfoxylate	2.50 mg
Disodium edetate	0.10 mg

Colourless to yellow solution, clear and free from particles.

3. TARGET SPECIES

Cattle, pigs and horses

4. INDICATIONS FOR USE

Cattle:	Reduction of clinical signs during respiratory infections in association with an appropriate anti-infective treatment.
Pigs:	Adjunctive therapy in the treatment of MMA (Mastitis-Metritis-Agalactia) syndrome in sows. Reduction of fever associated with respiratory disorders in association with an appropriate anti-infective treatment.
Horses:	Alleviation of inflammation and pain associated with musculoskeletal disorders. Alleviation of visceral pain associated with colic.

5. CONTRAINDICATIONS

Do not use in animals with liver, cardiac or renal disease.
Do not use in animals where there is the possibility of gastro-intestinal ulceration or bleeding.
Do not use the veterinary medicinal product where there are signs of blood dyscrasias or haemostasis alteration.
Do not use in cases of hypersensitivity to the active substance, to other NSAIDs or to any of the excipients.
Do not use the veterinary medicinal product in cattle within 48 hours before expected parturition in cows.
Do not use in pregnant mares.

Do not use in case of stomach cramps caused by ileus, associated with dehydration.
Do not use in animals that suffer chronic musculo-skeletal disorders.

6. SPECIAL WARNING(S)

Special warnings for each target species:
The underlying cause of inflammation or colic should be determined and treated concurrently with an appropriate therapy.
NSAIDs can cause phagocytosis inhibition and, therefore, in the treatment of inflammatory states associated with bacterial infections, appropriate concurrent antimicrobial therapy should be established.

Special precautions for use in animals:
Avoid use in dehydrated, hypovolaemic or hypotensive animals except in the case of endotoxaemia or septic shock.
During treatment, water consumption and hydration status of the animal should be monitored, since in cases of dehydration the risk of kidney damage increases.
Intra-arterial injection must be avoided in cows and horses. Ataxia, incoordination, hyperventilation, excitability and muscles weakness could appear as clinical signs. These signs are transitory and disappear in few minutes without using antidote therapy.
Use in any animal less than 6 weeks of age (cattle and horses) or in aged animals may involve additional risks. If such use cannot be avoided, animals may require a reduced dosage and careful clinical management.
It is preferable that NSAIDs which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.

The veterinary medicinal product must be injected slowly and at body temperature. Stop injection at the first signs of intolerance and treat shock if necessary.
In intramuscular administration in pigs, it should be avoided to deposit the drug in adipose tissue.
Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product can provoke reactions in sensitised individuals. People with known hypersensitivity to non-steroidal anti-inflammatory drugs and/or to propylene glycol should avoid contact with the veterinary medicinal product. Adverse reactions can be serious.
The veterinary medicinal product can cause skin and eye irritation. Avoid contact with skin and eyes Wash hands after using the product. In case of accidental skin exposure, wash the affected area immediately with plenty of water. In case of accidental eye contact rinse immediately with plenty of water. If skin and /or eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat or drink while using the veterinary medicinal product to avoid accidental ingestion. In case of accidental self-injection acute pain and inflammation may appear. Immediately clean and disinfect the wound, seek medical advice and show the package leaflet or the label to the physician.

Pregnancy, lactation and lay:
Studies in laboratory animals have shown evidence of foetotoxicity after oral (rabbit and rat) and intramuscular (rat) administration of flunixin at maternotoxic doses and also a lengthening of the duration of gestation (rat).
The safety of flunixin has not been established in pregnant mares and in breeding stallions and bulls. Do not use the veterinary medicinal product in these animals.
The safety of flunixin has been established in pregnant cows and sows and in breeding boars. The veterinary medicinal product can be used in these animals except for animals within 48 hours of parturition (see section 5 and 6).
In the 36 hours following parturition, the product should only be used according to the benefit/risk assessment by the responsible veterinarian and treated animals should be monitored for retention of the placenta.

Interaction with other medicinal products and other forms of interaction:
Pre-treatment with other anti-inflammatory substances may end up in additional or increase of adverse effects. Do not administer other NSAIDs concurrently or within at least 24 hours of each other. The pharmacokinetic properties of the other product should be taken into consideration before commencing treatment with this veterinary medicinal product.
The concurrent administration with corticoids may increase the toxicity of both products and increase the risk of gastrointestinal ulceration.
Flunixin may reduce the effect of some anti-hypertensive medicinal products, such as diuretics and beta blockers, by inhibition of prostaglandin synthesis.
Avoid concurrent administration of potentially nephrotoxic veterinary medicinal products, particularly aminoglycosides. Flunixin may reduce the renal excretion of certain veterinary medicinal products and increase their toxicity, such as for aminoglycosides.

Overdose (symptoms, emergency procedures, antidotes):
Overdose is associated with gastro-intestinal toxicity. Ataxia and incoordination may also occur.
In horses, after intravenous injection of three times the recommended dose, a transient increase in blood pressure may be observed.
In cattle, intravenous administration of three times the recommended dose did not lead to any adverse reaction.
In pigs, at 2 mg/kg twice daily, painful reaction at the injection site and a rise in leucocyte count has been reported.
Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. ADVERSE EVENTS

Horses, cattle, pigs

Undetermined frequency (cannot be estimated from the available data):	Haemorrhages[1], gastro-intestinal lesions (irritations, gastric ulcers)[1], vomiting[1], renal lesions[1] Slow down parturition[2], perinatal mortality (increase)[2] Retained placenta[3] Blood in faeces[7], diarrhoea[7]
Rare (1 to 10 animals / 10,000 animals treated):	Renal disorder[4], liver disorder[4] Shock[5] Anaphylactic-type reaction [6]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reactions[8]

[1] particularly in dehydrated or hypovolemic animals

[2] due to a tocolytic effect induced by the inhibition of the prostaglandin synthesis, responsible for the initiation of the parturition.

[3] if the product is used in the post-parturition period

[4] as with other NSAIDs

[5] Potentially lethal shock after intravenous administration, due to the presence of propylene glycol. Stop the administration and treat the shock symptoms in case of signs of general intolerance, if necessary.

[6] **Horses and Cattle only**: lethal outcome, collapse, mainly during rapid intravenous administration

[7] **Horses only:** after intravenous administration

[8] **Cattle only:** after intramuscular administration

If adverse reactions appear, stop the treatment and seek veterinary advice.

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.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Horses: Intravenous use.

Cattle: Intravenous or intramuscular use.
Pigs: Intramuscular use.

Horses:
- Alleviation of inflammation and pain associated with musculoskeletal disorders: 1 mg flunixin per kg body weight per day equivalent to 1 mL of the veterinary medicinal product per 50 kg body weight, IV, for 1-5 consecutive days.
- Alleviation of visceral pain associated with colic: 1 mg flunixin per kg body weight equivalent to 1 mL of the veterinary medicinal product per 50 kg body weight, IV. The treatment may be repeated once or twice if the symptoms reoccur.

Cattle:
- 2 mg flunixin per kg body weight per day equivalent to 2 mL of the veterinary medicinal product per 50 kg body weight, IV or IM, for 1-3 consecutive days. The maximal volume to be administered per injection site is 20mL.

Pigs:
- Adjunctive therapy in the treatment of MMA syndrome: 2 mg flunixin per kg body weight per day equivalent to 2mL of the veterinary medicinal product per 50 kg body weight, IM, for 1-3 consecutive days. If the injection volume exceeds 5mL, this volume should be divided into two doses, administered at two different injection sites.
- Reduction of fever associated with respiratory disorders: 2 mg flunixin per kg body weight equivalent to 2 mL of the veterinary medicinal product per 50 kg body weight, IM, once. If the injection volume exceeds 5mL, this volume should be divided into two doses, administered at two different injection sites.

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

The vial should not be broached more than 25 times. Therefore the user should select the most appropriate vial size according to the target species to be treated. When treating several animals in one run, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle should be removed after treatment.

9. ADVICE ON CORRECT ADMINISTRATION

During administration follow normal hygiene practices.

10. WITHDRAWAL PERIODS

Horses:
- Meat and offal: 10 days
- Milk: Not authorised for use in mares producing milk for human consumption.

Cattle:
- Following intravenous administration
    - Meat and offal: 10 days
    - Milk: 24 hours

- Following intramuscular administration
    - Meat and offal: 31 days
    - Milk: 36 hours

Pigs:

- Meat and offal: 20 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days

12. SPECIAL PRECAUTIONS FOR DISPOSALY

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
These measures should help to protect the environment. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.f

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 34534/5007

Pack sizes: Cardboard box containing one vial of 50, 100 or 250 mL.
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

23/09/2023

16. CONTACT DETAILS

Marketing authorisation holders and contact details to report suspected adverse reactions:

Marketing authorisation holder: Emdoka, John Lijsenstraat 16, B-2321 Hoogstraten, Belgium

Manufacturer responsible for batch release: Produlab Pharma bv, NL-4941 SJ Raamsdonksveer, Nederland

Local representatives and contact details to report suspected adverse reactions:

DUGV (UK) Ltd.
Union House
111 New Union Street
Coventry, CV1 2NT

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

17. OTHER INFORMATION

POM-V
For animal treatment only.
Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.

Approved 21 February 2024