ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pyrocam 15 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCE

One ml contains:

Active substance:

Meloxicam 15 mg

3. PACKAGE SIZE

1 L
250 ml
125 ml

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Shake well for at least 1 minute before use.
Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 5 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 1 months.
Once opened use by…..

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
Protect from frost.

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

Huvepharma NV

14. MARKETING AUTHORISATION NUMBER

Vm 30282/3004

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE BOTTLE 125 ml – 250 ml – 1 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pyrocam 15 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

One ml contains:

Active substance:

Meloxicam 15 mg

3. TARGET SPECIES

Pigs.

4. ROUTES OF ADMINISTRATION

Shake well for at least 1 minute before use.
Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 5 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 1 month.
Once opened use by….

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
Protect from frost.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Pyrocam 15 mg/ml oral suspension for pigs

2. Composition

One ml contains:

Active substance:

Meloxicam	15 mg

Excipients:

Methyl parahydroxybenzoate (E218)	1.8 mg
Propyl parahydroxybenzoate	0.2 mg

Pale yellow oral suspension

3. Target species

Pigs.

4. Indications for use

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation. For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (Mastitis-Metritis-Agalactia syndrome MMA) with appropriate antibiotic therapy.

5. Contraindications

Do not use in pigs suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:
If adverse events occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in very severely dehydrated, hypovolaemic or hypotensive pigs which require parenteral rehydration, as there may be a potential risk of renal toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause hypersensitivity (allergic reactions). People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) or parabens should avoid contact with the veterinary medicinal product.

This veterinary medicinal product can cause eye irritation. Personal protective equipment consisting of eye protection should be worn when handling the veterinary medicinal product. In case of contact with the eyes, immediately rinse thoroughly with water.

Avoid oral exposure, including hand-to-mouth contact. Wash hands after use. Do not eat, drink or smoke while handling the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Meloxicam may have adverse effects on pregnancy and/or embryofoetal development. Avoid dermal exposure including hand-to-mouth contact. Pregnant women or women attempting to conceive should wear impermeable gloves when administering the veterinary medicinal product.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

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

Overdose:
At 5 times the dose and 3 times the duration, no adverse effects have been observed in pigs.
In case of overdose, symptomatic treatment should be initiated.

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

7. Adverse events

None known.

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.

Oral suspension to be administered at a dosage of 0.4 mg/kg body weight (i.e. 2.7 ml/100 kg) in combination with antibiotic therapy, as appropriate. If required, a second administration of the veterinary medicinal product can be given after 24 hours. In cases of MMA with severely disturbed general demeanour (e.g. anorexia) the use of an injectable meloxicam product approved for the treatment of MMA is recommended.

9. Advise on correct administration

The veterinary medicinal product is intended for individual treatment only. To be administered preferably mixed with a small quantity of feed. Alternatively to be given prior to feeding, directly into the mouth.

Shake well for at least 1 minute before use.

The suspension should be measured using the syringe provided in the package. The syringe fits onto the bottle and the withdrawal of the dose should be performed on inverted bottle. The syringe has a body weight scale (in kg).

After administration of the veterinary medicinal product, wash the measuring syringe with warm water and let it dry.

10. Withdrawal periods

Meat and offal: 5 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.
Protect from frost.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 1 month.

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

Vm 30282/3004

Cardboard box with a HDPE-bottle closed with a two-part tamper and with a plastic measuring syringe (scale ranging from 20 kg to 300 kg, graduated at 20 kg intervals).

Pack sizes:
Bottle with 125 ml oral suspension.
Bottle with 250 ml oral suspension.
Bottle with 1000 ml oral suspension.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

For UK(NI) only: find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
<Tel: +32 3 288 18 49>
<E-mail: pharmacovigilance@huvepharma.com>

Manufacturer responsible for batch release:
Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

<Local representatives and contact details to report suspected adverse reactions:>

<17. Other information>

Approved 02 January 2024