[Version 9,03/2022], corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pyrocam 15 mg/ml oral suspension for pigs (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LV, LU, MT, NL, PL, PT, RO, SK, UK (NI))

Vetcam 15 mg/ml oral suspension for pigs (NO, SE and SL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Meloxicam 15 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	1.8 mg
Propyl parahydroxybenzoate	0.2 mg
Vanillin	
Microcrystalline cellulose	
Carmellose sodium	
Citric acid	
Sodium hydroxide	
Polysorbate 80	
Water, purified	

Pale yellow oral suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

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.

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

None known.

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.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The administration of the veterinary medicinal product to pigs at 5-fold overdosing of the recommended dose of 0.4 mg/kg b.w./day given for a duration longer than the recommended duration of treatment (6 days instead of 2 days at maximum) did not induce any toxicological or pathological changes.

In case of overdose, symptomatic treatment should be initiated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 5 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06.

4.2 Pharmacodynamics

Meloxicam is an enolcarboxamide NSAID of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B_2 induced by intravenous *E. coli* endotoxin administration in pigs.

4.3 Pharmacokinetics

After oral administration of the veterinary medicinal product at the dose of 0.4 mg meloxicam/kg body weight in pigs, meloxicam was well absorbed with a mean systemic bioavailability of 92%. Plasma concentrations reached a peak (mean Cmax of 0.8 µg/ml) after 2.25 hours on average.

From data obtained after IV injection it is known that meloxicam is distributed in the body with a low volume of distribution (0.37 L/kg on average), not exceeding the body fluids volume and a high binding rate (98%) to circulating plasma proteins.
After oral administration of the veterinary medicinal product, the highest meloxicam concentrations are found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle.

Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.
The mean plasma elimination half-life is approximately 3.25 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 1 month.

5.3 Special precautions for storage

Do not freeze.
Protect from frost.

5.4 Nature and composition of immediate packaging

Cardboard box with white, non-transparent round high density polyethylene (HDPE) bottle closed with a two-part tamper evident closure for child resistant packaging consisting of an outer white cap made of polypropylene, an internal natural colour screw closure made of HDPE and a mounted natural colour plug made of low density polyethylene, and with a plastic measuring syringe composed of a transparent body and a white plunger and with a measuring 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

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

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

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>