

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

FENDICAM 20 mg/ml solution for injection for cattle, pigs and horses

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains:

**Active substance:**

Meloxicam 20 mg/ml

**Excipient:**

Ethanol 159.8 mg/ml  
(as ethanol 96 per cent)

For the full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Solution for injection.  
Clear yellow solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cattle, pigs and horses.

#### **4.2 Indications for use, specifying the target species**

**Cattle:**

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.

For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.

For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.

**Pigs:**

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 toxæmia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

**Horses:**

For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.

For the relief of pain associated with equine colic.

**4.3 Contraindications**

See also section 4.7.

Do not use in horses less than 6 weeks of age.

Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

**4.4 Special warnings for each target species**

None.

**4.5 Special precautions for use**

i) Special precautions for use in animals

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

ii) Special precautions for 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 self-injection may give rise to pain. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

In view of the risk of accidental self-injection and the known adverse class-effects of NSAIDs and other prostaglandin inhibitors on pregnancy and/or embryofoetal development, the veterinary medicinal product should not be administered by pregnant women or women attempting to conceive.

iii) Other precautions

None.

#### 4.6 Adverse reactions (frequency and seriousness)

In cattle and pigs, subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.

In horses, a transient swelling at the injection site can occur but resolves without intervention.

In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

#### 4.7 Use during pregnancy, lactation or lay

**Cattle and pigs:**

Can be used during pregnancy and lactation.

**Horses:**

Do not use in pregnant or lactating mares.

See also section 4.3.

#### 4.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other NSAIDs or with anti-coagulant agents.

#### 4.9 Amount(s) to be administered and administration route

Maximum number of piercings is 14 for the 50 ml and 100 ml stoppers and 20 for the 250 ml stopper.

**Cattle:**

Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

**Pigs:**

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

**Horses:**

Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3.0 ml/100 kg body weight).

Avoid introduction of contamination during use.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

In the case of overdose, symptomatic treatment should be initiated.

#### **4.11 Withdrawal period(s)**

**Cattle:**

Meat and offal: 15 days.

Milk: 5 days (120 hours).

**Pigs:**

Meat and offal: 5 days

**Horses:**

Meat and offal: 5 days.

Not authorised for use in horses producing milk for human consumption.

### **5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:**

Anti-inflammatory and Anti-rheumatic products, non-steroids (oxicams).

**ATC Vet Code:**

QM01AC06.

#### **5.1 Pharmacodynamic properties**

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, anti-exudative, analgesic 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 B2 induced by *E. coli* endotoxin administration in calves, lactating cows and pigs.

#### **5.2 Pharmacokinetic particulars**

Absorption

After a single subcutaneous dose of 0.5 mg meloxicam/kg, C<sub>max</sub> values of 2.1 µg/ml and 2.7 µg/ml were reached after 7.7 hours and 4 hours in young cattle and lactating cows, respectively.

After two intramuscular doses of 0.4 mg meloxicam/kg, a C<sub>max</sub> value of 1.9 µg/ml was reached after 1 hour in pigs.

### Distribution

More than 98 % of meloxicam is bound to plasma proteins. The highest meloxicam concentrations are to be found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle and fat.

### Metabolism

Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile whereas urine contains only traces of the parent compound. In pigs, bile and urine contain only traces of the parent compound. 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 metabolism in horses has not been investigated.

### Elimination

Meloxicam is eliminated with a half-life of 26 hours and 17.5 hours after subcutaneous injection in young cattle and lactating cows, respectively. In pigs, after intramuscular administration the mean plasma elimination half-life is approximately 2.5 hours.

In horses, after intravenous injection meloxicam is eliminated with a terminal half-life of 8.5 hours.

Approximately 50 % of the administered dose is eliminated via urine and the remainder via faeces.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Ethanol (96 per cent)  
Poloxamer 188  
Macrogol 400  
Glycine  
Sodium hydroxide (for pH adjustment)  
Hydrochloric acid, concentrated (for pH adjustment)  
Meglumine  
Water for injections.

### **6.2 Major incompatibilities**

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

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.  
Shelf life after first opening the immediate packaging: 28 days.

#### **6.4 Special precautions for storage**

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

#### **6.5 Nature and composition of immediate packaging**

Cardboard box with 1 colourless Type I glass injection vial containing 50 ml, 100 ml or 250 ml. Each vial is closed with a grey bromobutyl rubber stopper and sealed with an aluminium cap.  
Not all pack sizes may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

### **7. MARKETING AUTHORISATION HOLDER**

Chanelle Pharmaceuticals Manufacturing Ltd  
Loughrea  
Co. Galway  
Ireland

### **8. MARKETING AUTHORISATION NUMBER**

Vm 08749/4090

### **9. DATE OF FIRST AUTHORISATION**

28 September 2016

### **10. DATE OF REVISION OF THE TEXT**

September 2021

Approved 10 September 2021

