

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

Rheumocam 15 mg/ml oral suspension for horses

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

One ml contains:

### **Active substance:**

Meloxicam 15 mg

### **Excipient:**

Sodium benzoate 5 mg

For the full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Oral suspension.

Honey flavoured, white to off-white viscous oral suspension.

## **4. CLINICAL PARTICULARS**

### **4.1 Target species**

Horses

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

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

### **4.3 Contraindications**

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.

### **4.4 Special warnings**

None.

### **4.5 Special precautions for use**

#### Special precautions for use in animals

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

## Special precautions to be taken by 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.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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

Isolated cases of adverse reactions typically associated with NSAIDs were observed in clinical trials (slight urticaria, diarrhoea). Symptoms were reversible. In very rare cases 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.

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 treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

Laboratory studies in cattle have not provided any evidence for teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in horses. Therefore the use in this species is not recommended during pregnancy and lactation.

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

Do not administer concurrently with glucocorticoids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

### **4.9 Amounts to be administered and administration route**

To be administered either mixed with food or directly into the mouth at a dosage of 0.6 mg/kg body weight, once daily, up to 14 days. In case the product is mixed with food, it should be added to a small quantity of food, prior to feeding.

The suspension should be given using the Rheumocam measuring syringe provided in the package. The syringe fits onto the bottle and has a 2 ml scale.

Shake well before use.

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)**

Meat and offal: 3 days.

Not authorised for use in lactating animals producing milk for human consumption.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotheapeutic group: Anti-inflammatory and Anti-rheumatic products, non-steroids (oxicams).  
ATCvet 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, 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<sub>2</sub> induced by intravenous *E. coli* endotoxin administration in calves and pigs.

### 5.2 Pharmacokinetic particulars

#### Absorption

When the product is used according to the recommended dosage regime, the oral bioavailability is approximately 98%. Maximal plasma concentrations are obtained after approximately 2–3 hours. The accumulation factor of 1.08 suggests that meloxicam does not accumulate when administered daily.

#### Distribution

Approximately 98% of meloxicam is bound to plasma proteins. The volume of distribution is 0.12 l/kg.

#### Metabolism

The metabolism is qualitatively similar in rats, mini-pigs, humans, cattle and pigs, although quantitatively there are differences. The major metabolites found in all species were the 5-hydroxy- and 5-carboxy- metabolites and the oxalyl- metabolite. The metabolism in horses was not investigated. All major metabolites have been shown to be pharmacologically inactive.

#### Elimination

Meloxicam is eliminated with a terminal half-life of 7.7 hours.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Saccharin sodium  
Carmellose sodium  
Silica, colloidal anhydrous  
Citric acid monohydrate  
Sorbitol, liquid (non-crystallising)  
Disodium phosphate dodecahydrate  
Sodium benzoate  
Honey aroma  
Purified water

### 6.2 Major incompatibilities

None known.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening of the immediate packaging: 3 months.

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

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

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.

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

HDPE bottle containing 100 or 250 ml with a tamper proof child resistant closure and a polypropylene measuring syringe.

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**

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 Limited  
Loughrea,  
Co. Galway,  
Ireland.

## **8. MARKETING AUTHORISATION NUMBERS**

EU/2/07/078/009 100 ml

EU/2/07/078/010 250 ml

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 10/01/2008.

Date of last renewal: 18/12/2012.

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

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

## **PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.