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**EPAR summary for the public**

**Metacam**

meloxicam

This is a summary of the European public assessment report (EPAR) for Metacam. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Metacam.

For practical information about using Metacam, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

**What is Metacam and what is it used for?**

Metacam is a veterinary medicine that contains the active substance meloxicam.

In cattle, Metacam is used together with appropriate antibiotic therapy, to reduce clinical signs of disease, in acute (short-term) respiratory infection (infection of the lungs and airways). It can be used in diarrhoea in combination with oral re-hydration therapy (medicines given by mouth to restore water levels in the body) to reduce clinical signs of the disease in calves of over one week of age and young, non-lactating cattle. It can be used for the relief of post-operative pain following dehorning in calves and as supportive therapy in the treatment of acute mastitis (inflammation of the udder), in combination with antibiotics.

In pigs, Metacam is used in non-infectious locomotor disorders (diseases that affect the ability to move) to reduce the symptoms of lameness and inflammation, for the relief of post-operative pain associated with minor soft tissue surgery such as castration, and for supportive therapy together with appropriate antibiotic therapy in the treatment of diseases that occur after farrowing (giving birth) such as puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome, a bacterial infection of the udder and/or the womb).

In horses, Metacam is used for the relief of pain associated with colic (abdominal pain) and for the alleviation of inflammation and relief of pain in both acute and chronic (long-term) musculo-skeletal disorders (disorders affecting the muscles and bones).
In dogs, Metacam is used to reduce post-operative pain and inflammation following orthopaedic (e.g. fracture operation) and soft tissue surgery. Moreover, it is used for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

In cats, Metacam is used to reduce post-operative pain and inflammation after ovariohysterectomy (spay operation), orthopaedic and minor soft tissue surgery. Moreover, it is used for the alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders.

**How is Metacam used?**

Metacam is available as an oral suspension, a solution for injection and chewable tablets. The formulation and dose to use depends on the animal, its bodyweight and the condition being treated. Injections may be into a vein, muscles or under the skin, depending on the species and the condition being treated.

Metacam can only be obtained with a prescription. For further information, see the package leaflet.

**How does Metacam work?**

Metacam contains meloxicam, which belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Meloxicam acts by blocking an enzyme called cyclooxygenase which is involved in the production of prostaglandins. As prostaglandins are substances that trigger inflammation, pain, exudation (fluid that leaks out of blood vessels during an inflammation) and fever, meloxicam reduces these signs of disease.

**What benefits of Metacam have been shown in studies?**

**Cattle**

The effectiveness of Metacam injection, in combination with antibiotic therapy, was studied in cattle with acute respiratory infection. 326 cattle received Metacam given as an injection together with antibiotic therapy whilst 326 cattle received a dummy injection and antibiotic therapy. Metacam injection in cattle significantly improved clinical signs of respiratory infection and reduced fever compared with antibiotics alone.

Another study in cattle involved 501 calves with diarrhoea. Animals received either Metacam injection or a dummy injection. All calves were given oral rehydration therapy and antibiotics. The main measure of effectiveness was based on clinical signs of diarrhoea and the animal’s behaviour, feed intake, body temperature, respiratory rate, heart rate and general condition. Calves treated with Metacam showed a significant improvement in their signs of diarrhoea compared with the control group.

Metacam injection was studied in 60 calves with one group receiving Metacam and local anaesthetic and one group receiving a placebo (dummy) injection and local anaesthetic prior to dehorning. The main measure of effectiveness was reduction in pain sensitivity and the study showed Metacam to have an effect in reducing pain associated with the dehorning procedure.

Metacam injection in combination with antibiotic therapy was investigated in a study involving 240 cattle with acute mastitis. In addition to antibiotic therapy animals either received a single injection of Metacam or flunixin (another NSAID) for up to 5 days. The main measure of effectiveness was based
on their general condition, milk appearance and signs of udder inflammation. Metacam was comparable to the control product in providing supportive treatment of acute mastitis in cattle.

**Pigs**

The effectiveness of Metacam injection was studied in 209 pigs with non-infectious locomotor disorders. Pigs either received Metacam or a placebo injection. The main measure of effectiveness was based on signs of lameness. Metacam significantly reduced lameness with 49% of the Metacam treated pigs with no lameness compared with 27% of the pigs which received the placebo treatment.

A study in 150 piglets was carried out to compare the effects of Metacam injection with placebo when given before castration. The main measure of effectiveness was blood cortisol levels 30 minutes after surgery. Cortisol is a measure of stress. Metacam treated piglets had significantly reduced blood cortisol levels 30 minutes after castration compared with the control group.

A study in 187 sows with puerperal septicaemia and toxaemia compared Metacam with flunixin (another NSAID). All sows also received antibiotics. Metacam was comparable to flunixin in treating signs of infection and inflammation associated with puerperal septicaemia and toxaemia.

**Horses**

Metacam injection was compared with vedaprofen (another NSAID) for pain relief associated with equine colic in 269 horses. The main measure of effectiveness was based on signs of colic. Metacam was comparable to vedaprofen in reducing pain associated with equine colic.

Metacam oral suspension was studied for treatment of musculoskeletal disorders associated with lameness in two studies and compared to treatment with vedaprofen. The main measure of effectiveness was a reduction of lameness. Metacam showed improved lameness in horses at day 14 and at the final follow-up examination 2–4 days later than the vedaprofen treated group whilst the second study showed Metacam to be comparable to vedaprofen.

**Dogs**

A number of studies were conducted in dogs with acute and chronic locomotor disorders with both oral and injectable Metacam. The studies with chronic locomotor disorders showed Metacam to be effective.

In one study three different meloxicam treatment schedules for acute locomotor disorders were compared. The main measure of effectiveness was based on improvements in mobility, local inflammation and pain. This study showed that the dogs receiving meloxicam injection followed by oral doses had the highest score of excellent/good.

**Cats**

Metacam injection was studied in 76 cats undergoing ovariohysterectomy. 37 cats received Metacam and 39 cats received carprofen (another NSAID) by subcutaneous (under the skin) injection immediately after induction of anaesthesia. The main measure of effectiveness was the assessment of pain score at various time points up to 20 hours post-surgery. Metacam 5 mg/ml solution for injection was comparable to carprofen in reducing post-operative pain in cats following ovariohysterectomy.

A study was carried out in cats with acute musculo-skeletal disorders. Metacam oral suspension was given for 5 days and compared with ketoprofen (another NSAID). The main measure of effectiveness was based on an improvement in lameness and pain. Metacam oral suspension was also comparable to ketoprofen for treatment of acute musculo-skeletal disorders in cats.
Another study was carried out in cats with chronic musculo-skeletal disorders. 46 cats received Metacam oral suspension for 28 days whilst 48 cats received placebo oral suspension. The main measure of effectiveness was reduction in mobility, posture and pain. Metacam was effective from day 0–14 compared to the control group.

**What are the risks associated with Metacam?**

In cattle and pigs, Metacam is well tolerated; only a slight temporary swelling at the injection site following subcutaneous administration was observed in most cattle studied in laboratory conditions.

In horses, anaphylactoid (allergic) reactions can occur and should be treated according to the signs presented. A temporary swelling at the injection site can occur but resolves without intervention. In addition slight urticaria (itchy rash) and diarrhoea can occur which are both typical side effects of NSAIDs and which resolve by themselves. In very rare cases loss of appetite, lethargy, abdominal pain and colitis (inflammation of the lower part of the gut) have been reported.

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

In dogs and cats, occasional side effects of Metacam are those seen with NSAIDs, such as loss of appetite, vomiting, diarrhoea, blood appearing in the stools, apathy (lack of vitality) and kidney failure. In very rare cases anaphylactoid reactions and elevated liver enzymes have been reported. These side effects resolve once treatment has stopped. In very rare cases, they may be serious or fatal.

In very rare cases, in dogs, haemorrhagic diarrhoea (bloody diarrhoea), haematemesis (vomiting blood) or gastrointestinal ulceration (ulcer in the gut) have been reported. These side effects occur usually within the first week of treatment and are generally transient (temporary).

**What are the precautions for the person who gives the medicine or comes into contact with the animal?**

People who are hypersensitive (allergic) to NSAIDs should avoid contact with Metacam. If the product is accidentally swallowed or self-injected by a person, the advice of a doctor should be sought immediately.

The 40 mg/ml solution for injection should not be handled by pregnant women or women attempting to conceive as it may affect the development of the baby in the womb.

**What is the withdrawal period in food-producing animals?**

The withdrawal period is the time allowed after administration of the medicine before an animal can be slaughtered and the meat used for human consumption. It is also the time required after administration of a medicine before milk may be used for human consumption.

**Cattle**

The withdrawal period is 15 days for meat and 5 days for milk.

**Pigs**

The withdrawal period for meat is 5 days.
Horses

For the 20 mg/ml and 40 mg/ml solution for injection the meat withdrawal period is 5 days and for the 15 mg/ml oral suspension it is 3 days. The product is not authorised to use in horses producing milk for human consumption.

Why is Metacam approved?

The Agency’s Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Metacam’s benefits are greater than its risks and they recommended that it be approved for use in the EU.

Other information about Metacam

The European Commission granted a marketing authorisation valid throughout the European Union for Metacam on 7 January 1998.

The full EPAR for Metacam can be found on the Agency’s website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Metacam, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in June 2016.