



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/CVMP/259397/2006
EMA/V/C/000033

Metacam (*meloxicam*)

An overview of Metacam and why it is authorised in the EU

What is Metacam and what is it used for?

Metacam is an anti-inflammatory medicine used in cattle, pigs, horses, dogs, cats and guinea pigs.

In cattle, Metacam is used together with antibiotics, to reduce clinical signs such as fever and inflammation 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 to relieve 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 lameness and inflammation, relieve post-operative pain associated with minor soft tissue surgery such as castration, and for supportive therapy together with antibiotics in the treatment of diseases that occur after farrowing (giving birth) such as puerperal septicaemia and toxoemia (mastitis-metritis-agalactia syndrome, a bacterial infection of the udder and/or the womb).

In horses, Metacam is used to relieve pain associated with colic (abdominal pain) and to alleviate inflammation and 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 to alleviate 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 to alleviate pain and inflammation in acute and chronic musculo-skeletal disorders.

In guinea pigs, Metacam is used to reduce post-operative pain after soft tissue surgery such as castration.

Metacam contains the active substance meloxicam.



How is Metacam used?

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

Metacam can only be obtained with a prescription. For further information about using Metacam, see the package leaflet or contact your veterinarian or pharmacist.

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 placebo (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 placebo 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 injection and local anaesthetic prior to dehorning. The study showed Metacam to be effective 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. 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 levels of the stress hormone cortisol 30 minutes after surgery. Metacam treated piglets had significantly reduced blood cortisol levels (which indicates that they were exposed to lower levels of stress) 30 minutes after castration compared with the control group.

A study in 187 sows with puerperal septicaemia and toxemia 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 toxemia.

Horses

Metacam injection was compared with vedaprofen (another NSAID) for pain relief associated with equine colic in 269 horses. Both medicines were comparable 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. Metacam 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 study showed that the dogs receiving meloxicam injection followed by oral doses had the best results in improving mobility based on a standard scoring system.

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 receiving 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). Metacam oral suspension was comparable to ketoprofen in improving lameness and pain.

A study was also 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. Metacam was effective in improving mobility and reducing pain from day 0–14 compared to the control group.

Guinea pigs

A laboratory study in 30 guinea pigs compared Metacam oral suspension with placebo given about 45 minutes before surgical castration and on each of the following two days. Guinea pigs treated with Metacam had significantly higher frequency of feed intake (240 events) over three days, indicating that their pain was reduced, compared with guinea pigs given placebo (207 events).

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.

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).

For the full list of restrictions, see the package leaflet.

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 accidental self-injection 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 in the EU?

The European Medicines Agency decided that Metacam's benefits are greater than its risks and that it can be authorised for use in the EU.

Other information about Metacam

Metacam received a marketing authorisation valid throughout the EU for Metacam on 7 January 1998.

Further information on Metacam can be found on the Agency's website: [ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports](http://ema.europa.eu/Find_medicine/Veterinary_medicines/European_public_assessment_reports).

This summary was last updated in March 2018.