Metacam® 1.5 mg/ml oral suspension for dogs and Metacam® 0.5 mg/ml oral suspension for cats - sub-dispensing information

Where it is possible for you to obtain a supply of the appropriate size of Metacam® oral suspension this is always the preferred option. Where this is not possible we understand that you may wish to sub-dispense from larger bottles which are licensed for the appropriate species. Whilst the long-term stability of Metacam® oral suspension has only been assessed within the original packaging, over the years we have received many anecdotal reports of it being sub-dispensed and we are not aware of any issues associated with this.

As with any medication dispensed outside of its original packaging, Metacam® oral suspension should be provided in an appropriate child-proof container (ideally opaque, like the original bottle) and appropriately labelled. For further information on dispensing medications and labelling, please refer to the Veterinary Medicines Regulations and the RCVS Guidelines (UK) or the Animal Remedies Regulations and the Veterinary Council (Ireland). Sufficient written information must be provided to the pet owner to enable safe use and to help facilitate this, an electronic copy of the package leaflets can be accessed at: bit.ly/BIAHSupport

If possible, when sub-dispensing we recommend providing the pet owner with the appropriate Metacam® dosing syringe to help ensure accurate dosing. Dosing syringes for small dogs (<10 kg) can be obtained from your wholesaler. If you require additional dosing syringes for dogs over 10 kg or for cats please contact your Boehringer Ingelheim territory manager. To help protect the supply of syringes, where a pet owner already has a Metacam dosing syringe for the pet that is being treated, we recommend requesting that they keep it provided the writing on it is still clear. If you are unable to obtain an appropriate sized Metacam® dosing syringe then an appropriately sized regular syringe may be used alongside carefully explained and written instructions for the owner on the total volume required per dose. This is always important, but especially so when a pet owner has previously used the weight-calibrated syringes and therefore may not automatically realise the difference. The volume required per dose can be calculated using the following information:

Metacam® 1.5 mg/ml oral suspension for dogs:
Initial dose (day one) (0.2 mg/kg) = 0.13 ml per kg of body weight
Routine maintenance dose (0.1 mg/kg) = 0.07 ml per kg of body weight

Metacam® 0.5 mg/ml oral suspension for cats:
Initial dose (day one) - acute musculo-skeletal disorders (0.2 mg/kg) = 0.4 ml per kg bodyweight
Initial dose (day one) - chronic musculo-skeletal disorders (0.1 mg/kg) = 0.2 ml per kg of bodyweight
Routine maintenance dose (0.05 mg/kg) = 0.1 ml per kg of body weight

Further information regarding the dispensing and labelling of medications can be found at:

UK:
The RCVS code of Professional Conduct for Veterinary Surgeons: https://www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/veterinary-medicines/

The Veterinary Medicines Regulations: https://www.gov.uk/guidance/veterinary-medicines-regulations

Ireland:
The Veterinary Council: https://www.vci.ie/

The Animal Remedies Regulations:
http://www.irishstatutebook.ie/eli/2007/si/786/made/en/print

Further information

We hope this information is useful. You may also wish to visit the Boehringer Academy, which now provides even more information relating to Boehringer's products and the related disease areas. You can use the smart search facility to find answers to your questions, watch bitesize videos between your consultations or view high quality and independent CPD webinars at a time that is convenient to you. The Boehringer Academy can be accessed by visiting www.boehringer-academy.co.uk.

TECHNICAL SERVICES

If you have any further questions, please do not hesitate to call our Technical Services Team on 01344 746957 (UK) or 01 291 3985 (IE) or email vetenquiries@boehringer-ingelheim.com.

We also provide a 24/7 emergency advice service. If you have an emergency outside office hours, just call one of the numbers above and follow the instructions.

A technical information service from Boehringer Ingelheim Animal Health UK Ltd, makers of Metacam® solution for injection, oral suspension and chewable tablets. Metacam® contains meloxicam. Metacam® 1.5 mg/ml oral suspension for dogs is indicated for alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs. Metacam® 0.5 mg/ml oral suspension for cats and guinea pigs is indicated for: alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery; alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders in cats; and alleviation of mild to moderate post-operative pain associated with soft tissue surgery such as male castration in guinea pigs. UK: POM-V IE: POM. For information about side effects, precautions, warnings and contraindications please refer to the product packaging and package leaflet. Advice should be sought from the prescriber. Further information available in the SPC (UK/IE: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/veterinary/000033/WC500065777.pdf) or from Boehringer Ingelheim Animal Health UK Ltd, RG12 8YS, UK. UK Tel: 01344 746959 (sales) or 01344 746957 (technical), IE Tel: 01 291 3985 (all queries). Email: vetenquiries@boehringer-ingelheim.com. Metacam® is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, used under licence. Date of preparation: July 2020. UI-PVT-0121-2020. Use Medicines Responsibly.

159610-002

Metacam®

0.5 mg/ml

oral suspension for cats and guinea pigs

Meloxicam

EN

Boehringer Ingelheim

Marketing authorisation holder and manufacturer responsible for batch release
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Active substance
One ml contains:
Meloxicam 0.5 mg
(equivalent to 0.017 mg per drop)

Yellowish viscous oral suspension with a green tinge.

Indications
Cats: Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery.

Alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders in cats.

Guinea pigs: Alleviation of mild to moderate post-operative pain associated with soft tissue surgery such as male castration.

Contraindications
Do not use in pregnant or lactating animals.
Do not use in cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats less than 6 weeks of age.
Do not use in guinea pigs less than 4 weeks of age.

Adverse reactions
In cats, typical adverse reactions of non-steroidal anti-inflammatory Drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have very rarely been reported from post-marketing safety experience.
Gastrointestinal ulceration and elevated liver enzymes were reported in very rare cases from post-marketing safety experience.

These side effects are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

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 reactions during)
- 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).

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 inform your veterinary surgeon.

Target species
Cats and guinea pigs

Dosage for each species, route and method of administration
Cats
Dosage
Post-operative pain and inflammation following surgical procedures
After initial treatment with Metacam® 2 mg/ml solution for injection for cats, continue treatment 24 hours later with Metacam® 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight. The oral follow-up dose may be administered once daily (at 24-hour intervals) for up to 4 days.

Acute musculo-skeletal disorders
Initial treatment is a single oral dose of 0.2 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a dose of 0.05 mg meloxicam/kg body weight for as long as acute pain and inflammation persist.

Chronic musculo-skeletal disorders
Initial treatment is a single oral dose of 0.1 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.05 mg meloxicam/kg body weight.

A clinical response is normally seen within 7 days. Treatment should be discontinued after 14 days at the latest if no clinical improvement is apparent.

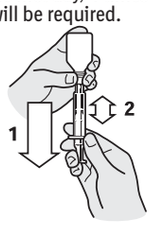
Route and method of administration
To be administered orally either mixed with food or directly into the mouth.
The suspension can be given using the drop dispenser of the bottle for cats of any body weight. Alternatively and for cats with a body weight of at least 2 kg, the measuring syringe provided in the package can be used.
Particular care should be taken with regard to the accuracy of dosing.
The recommended dose should not be exceeded.

Dosing procedure using the drop dispenser of the bottle
Dose of 0.2 mg meloxicam/kg body weight:
12 drops /kg body weight.
Dose of 0.1 mg meloxicam/kg body weight:
6 drops /kg body weight.
Dose of 0.05 mg meloxicam/kg body weight:
3 drops /kg body weight.

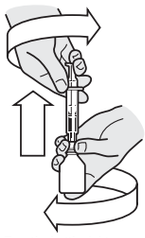
Dosing procedure using the measuring syringe
The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the dose of 0.05 mg meloxicam/kg bodyweight. Thus for initiation of the treatment of chronic musculo-skeletal disorders on the first day, twice the maintenance volume will be required.

For initiation of the treatment of acute musculo-skeletal disorders on the first day, 4 times the maintenance volume will be required.

Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the drop dispenser of the bottle by gently pushing.



Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to your cat´s bodyweight in kilograms.



Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle

By pushing the plunger in empty the contents of the syringe onto the food or directly into the mouth.

Guinea pigs
Dosage
Post-operative pain associated with soft tissue surgery
Initial treatment is a single oral dose of 0.2 mg meloxicam/kg body weight on day 1 (pre-surgery). Treatment is to be continued once daily by oral administration (at 24-hours intervals) at a dose of 0.1 mg meloxicam/kg body weight on day 2 to day 3 (post-surgery).

The dose can, at the discretion of the veterinarian, be titrated up to 0.5 mg/kg in individual cases. The safety of doses exceeding 0.6 mg/kg has, however, not been evaluated in guinea pigs.

Route and method of administration
The suspension should be given directly into the mouth using a standard 1 ml syringe graduated with ml scale and 0.01 ml increments.

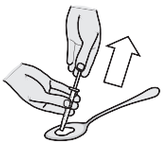
Dose of 0.2 mg meloxicam/kg body weight: 0.4 ml/kg body weight
Dose of 0.1 mg meloxicam/kg body weight: 0.2 ml/kg body weight

Use a small container (e.g. a teaspoon) and drop Metacam® oral suspension into the container (it is advised to dispense a few drops more than required into the small container). Use a standard 1 ml syringe to draw up Metacam® according to the bodyweight of the guinea pig. Administer Metacam® with the syringe directly into the mouth of the guinea pig. Wash the small container with water and dry prior to the next use.

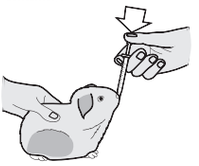
Do not use the cat syringe with the kg-body weight scale and the cat pictogram for guinea pigs.

Shake bottle well.
Push down and unscrew bottle top.

Use a small container (e.g. a teaspoon) and drop Metacam® oral suspension into the container (it is advised to dispense a few drops more than required into the small container).



Use the 1 ml standard syringe and draw up the required volume of Metacam® oral suspension which corresponds to the body weight of the guinea pig.



By pushing the plunger in empty the contents of the syringe directly into the mouth of the guinea pig.

Advice on correct administration
Please carefully follow the instructions of the veterinarian. Shake well before use.
Avoid introduction of contamination during use.

Withdrawal period
Not applicable.

Special storage precautions
Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

Shelf life after first opening the container:
3 ml bottle: 14 days
10 ml, 15 ml and 30 ml bottles: 6 months.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the vial after EXP.

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

Post-operative use in cats and guinea pigs
In case additional pain relief is required, multimodal pain therapy should be considered.

Chronic musculoskeletal disorders in cats
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

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

This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

Pregnancy and lactation
See section "Contraindications".

Interactions with other medicinal products and other forms of interaction
Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects.

Metacam® must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic drugs should be avoided.

In cats, pre-treatment with anti-inflammatory substances other than Metacam® 2 mg/ml solution for injection for cats at a single dose of 0.2 mg/kg may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacological properties of the products used previously.

Overdose (symptoms, emergency procedures, antidotes)
Meloxicam has a narrow therapeutic safety margin in cats and clinical signs of overdose may be seen at relatively small overdose levels.

In case of overdose, adverse reactions, as listed in section "Adverse reactions", are expected to be more severe and more frequent. In case of overdose symptomatic treatment should be initiated.

In guinea pigs, an overdose of 0.6 mg/kg body weight administered during 3 days followed by a dose of 0.3 mg/kg during 6 additional days did not cause adverse events typical for meloxicam. The safety of doses exceeding 0.6 mg/kg has not been evaluated in guinea pigs.

Special precautions for the disposal of unused product or waste materials
Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Date on which the package leaflet was last approved
05/2020

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.emea.europa.eu/.

Other information
3 ml, 10 ml, 15 ml or 30 ml bottle.
Not all pack sizes may be marketed.

For animal treatment only.

POM
IE: Prescription Only Medicine

POM-V
UK: To be supplied only on veterinary prescription.

159615-003

Metacam®
1.5 mg/ml
oral suspension for dogs
Meloxicam

EN

Boehringer Ingelheim

Marketing authorisation holder and manufacturer responsible for batch release
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Active substance
One ml contains:
Meloxicam 1.5 mg
(equivalent to 0.05 mg per drop)

Yellowish viscous oral suspension with a green tinge.

Indications
Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

Contraindications
Do not use in pregnant or lactating animals.
Do not use in dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs less than 6 weeks of age.

Adverse reactions
Typical adverse reactions of non-steroidal anti-inflammatory drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have very rarely been reported from post-marketing safety experience.
Very rare cases of haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported from post-marketing safety experience.

These side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

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 reactions)
- 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).

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 inform your veterinary surgeon.

Target species
Dogs

Dosage, route and method of administration
Dosage
Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight.

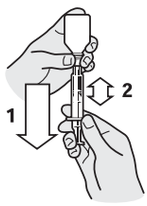
For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose of Metacam® can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

Method and route of administration
Shake well before use. To be administered orally either mixed with food or directly into the mouth.
The suspension can be given using either the drop dispenser of the bottle (for very small breeds) or the measuring syringe provided in the package.

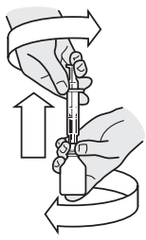
Dosing procedure using the drop dispenser of the bottle:
Initial dose: 4 drops/kg body weight
Maintenance dose: 2 drops/kg body weight.

Dosing procedure using the measuring syringe:
The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the maintenance dose. Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.

Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the drop dispenser of the bottle by gently pushing.



Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to your dog's body weight in kilograms.



Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle.

By pushing the plunger in empty the contents of the syringe onto the food or directly into the mouth.

Alternatively therapy may be initiated with Metacam® 5 mg/ml solution for injection.

A clinical response is normally seen within 3-4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

Advice on correct administration
Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian.
Avoid introduction of contamination during use.

Withdrawal period
Not applicable.

Special storage precautions
Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf life after first opening the container: 6 months.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after EXP.

Special warnings
Special precautions for use in animals
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.
This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Metacam® 0.5 mg/ml oral suspension for cats should be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.
This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

Pregnancy and lactation
See section "Contraindications".

Interaction with other medicinal products and other forms of interaction
Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects.
Metacam® must not be administered in conjunction with other NSAIDs or glucocorticosteroids.
Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacological properties of the products used previously.

Overdose (symptoms, emergency procedures, antidotes)
In case of overdose symptomatic treatment should be initiated.

Special precautions for the disposal of unused product or waste materials
Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Date on which the package leaflet was last approved
05.2020

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

Other information
10 ml, 32 ml, 100 ml or 180 ml bottle. Not all pack sizes may be marketed.

For animal treatment only.

POM
IE: Prescription Only Medicine

POM-V
UK: To be supplied only on veterinary prescription.

Important product update from Boehringer Ingelheim Animal Health UK Limited

Pexion®

Disruption to Pexion® supply

Due to the impact of the Covid-19 pandemic at one of our manufacturing sites, we are facing a period of temporary supply disruption with Pexion®, our product for canine idiopathic epilepsy and noise phobia. The manufacturing site that produces Pexion® for the UK, Ireland and the rest of Europe is located in a region which is badly impacted by the Covid-19 pandemic. Please be reassured that we are doing all we can to minimise this impact.

We understand how critical Pexion® is to your patients, and we have taken immediate steps to help protect supply for those patients most in need. With immediate effect, Pexion® 100 mg and 400 mg tablets will be allocated by our Technical Services Team on a case-by-case basis according to clinical need until we can re-establish supply. During the call we may ask you to transition suitable cases from Pexion® 400 mg tablets to 100 mg tablets to protect supply for larger dogs and those on significant doses. Veterinary practices can access email templates, which may be helpful to ask clients to place repeat prescription requests for Pexion® early, via this link: **bit.ly/BIAHSupport**

To ensure product availability for critical patients, we would kindly request that you:

Please avoid starting any new patients on Pexion® until the supply situation is resolved

We understand the challenges your practice has faced during the Covid-19 pandemic and the pressure it has put on you and your team. We are sorry to cause any further disruption during these difficult times. Thank you for your continued support and understanding.

If you have a specific case for which you require Pexion® 100 mg or 400 mg tablets, please contact our **Technical Services Team on 01344 746957.**

Boehringer Ingelheim