MeloxiLab-Rat

(meloxicam extended-release injection)

2 mg/mL

For subcutaneous use in rats only

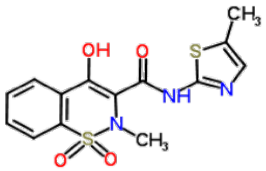
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
LEGAL STATUS: In order to be legally marketed, a new animal drug intended for a minor species must be Approved, Conditionally Approved, or Indexed by the Food and Drug Administration.
THIS PRODUCT IS INDEXED—MIF#900-033. Extra label use is prohibited.

This product is not to be used in animals intended for use as food for humans or food-producing animals.

DESCRIPTION:

MeloxiLab-Rat is a sterile injectable solution which contains meloxicam as the active ingredient. It is formulated in a polymer that provides the sustained release characteristics, consisting of a biodegradable liquid polymer dissolved in a biocompatible solvent. The polymer used in the MeloxiLab-Rat product is a copolymer of lactide and caprolactone . Each ml contains 2 mg meloxicam. Meloxicam is 4-hydroxy-2methyl-N-(5-methyl-2-thiazolyl)-2H-1,2- benzothiazine-3-carboxamide-1,1-dioxide. The molecular mass of meloxicam is 351.395 g/mol; the empirical formula is C14H13N3O4S2.

STRUCTURAL FORMULA:



INDICATIONS:

MeloxiLab-Rat is indicated for the control of post-procedural pain in rats.

DOSAGE AND ADMINISTRATION:

Rats should be dosed at 4 mg/kg body weight. A single injectable dose administered following a surgical procedure may provide up to 48 hours of pain control (Seymour, 2016). The entire dose should be administered subcutaneously, generally in the dorsal mid-scapular region. To avoid any leakage of polymer contents out of the injection site, the injection should be given in the following manner.

1. Remove a small amount of fur at the injection site.
2. Prep the skin with 70% alcohol.
3. Using a 25 gauge needle, or a needle of appropriate size on the dosing syringe to ensure precise dosing, tent the skin and insert the needle full length (5/8") under the skin.
4. Inject the formulation slowly over 10-15 seconds, and slowly withdraw the needle while pinching the skin at the needle exit site.
5. Continue to pinch the skin for 5-10 seconds after needle withdrawal.

CONTRAINDICATIONS:

Rats with known hypersensitivity to meloxicam should not receive MeloxiLab-Rat.

WARNINGS:

Not for use in humans. Keep this and all medications out of reach of children. For subcutaneous injectable use in rats under the supervision of a licensed veterinarian.

PRECAUTIONS:

Safety of systemic exposure to repeated dosing of MeloxiLab-Rat has not been evaluated.

As a class, cyclo-oxygenase inhibitory NSAIDs such as MeloxiLab-Rat, may be associated with gastrointestinal, renal, and hepatic toxicity. Patients at greatest risk for adverse events are those that are dehydrated, on concomitant diuretic therapy, or those with existing renal, cardiovascular, and/or hepatic dysfunction.

Concurrent administration of potentially nephrotoxic and hepatotoxic drugs should be carefully approached and monitored.

Anesthetic drugs may affect renal perfusion; approach concomitant use of anesthetics and NSAIDs cautiously. Appropriate monitoring procedures should be employed during all surgical procedures. The use of perioperative parenteral fluids is recommended to decrease potential renal complications when using NSAIDs. If additional pain medication is needed after a single, one-time dose of MeloxiLab-Rat, a non-NSAID class of analgesic may be necessary.

Do not use MeloxiLab-Rat concomitantly with other anti-inflammatory drugs, such as NSAIDs or corticosteroids. NSAIDs possess the potential to produce gastrointestinal ulcerations and/or perforations.

Safety has not been established for intravenous (IV) or intramuscular (IM) administration in rats.

The safe use of MeloxiLab-Rat has not been evaluated in breeding, pregnant, or lactating rats.

ADVERSE REACTIONS:

Adverse skin reactions around the injection site were observed in rats administered MeloxiLab-Rat at 4 mg/kg body weight. In a pilot study, 16/16 rats were observed to have skin lesions following a single subcutaneous injection of MeloxiLab-Rat at a dose of 4 mg/kg. Gross and histological findings showed erythema and localized inflammation, respectively, including 2 rats that developed draining tracts. The study reported that the median time rats developed a skin lesion was 3 days. (Stewart, 2020)"

CONTACT INFORMATION:

To report adverse reactions or to obtain a copy of the SDS for this product call Wildlife Pharmaceuticals, Inc. at 1-970-795-0920.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDAVETS or http://www.fda.gov/reportanimalae.

CLINICAL PHARMACOLOGY:

Pharmacokinetic parameters of MeloxiLab-Rat were investigated in 7 male Sprague Dawley rats following a single subcutaneous injection of 4 mg/kg of body weight. Peak plasma concentrations of 18.5 mcg/mL at day 1 with rapid decrease in plasma concentrations starting at 48 hours post-dose with 5.9 mcg/mL, followed by 2.9 mcg/mL at 72 hours and 2.4 mcg/mL at 96 hours (Seymour, 2016).

Gender differences in rat meloxicam pharmacokinetics have been observed in fasted albino rats after IV and PO dosing (Busch 1998). After IV dosing at 1 mg/kg, the observed AUC infinity values were significantly higher for female (three-fold) versus male rats, and after repeated oral dosing at 0.3 or 1 mg/kg, females had 2.5 – 3.9 higher AUC infinity values than males. These gender differences appear to be due to differences in the rate of formation of oxidative metabolites, especially the carboxylic acid that is formed on the thiazole methyl group. There have been no other clinical studies to further assess pharmacokinetic gender differences among target animal species nor its clinical significance for effectiveness or safety using this drug formulation.

HOW SUPPLIED:

MeloxiLab-Rat is supplied in a 5 mL clear glass vial containing 2 mg meloxicam per mL.

STORAGE INFORMATION:

Store at controlled room temperature 15-30°C (59-86°F). Protect from sunlight and prolonged exposure to excessive heat.

Lot #:

Expiration Date:

Label Revision Date:

Manufactured for

Wildlife Pharmaceuticals, Inc.
1230 W. Ash Street, Suite D, Windsor, CO 80550

REFERENCES:

1. Busch U, Schmid J, Heinzel, Schmaus H, Baierl J, Huber C, Roth W. 1998. Pharmacokinetics of meloxicam in animals and the relevance to humans. Drug Metabolism and Disposition. 26:576
2. Engelhardt G, Homma D, Schlegel K, Schnitzler C, Utzmann R. 1996. General pharmacology of meloxicam- Part II: Effects on blood pressure, blood flow, heart rate, ECG, respiratory minute volume and interactions with Paracetamol, Pirenzepine, Chlorthalidone, Phenprocoumon, and Tolbutamide. Gen Pharmac. 27(4):679.
3. Foley PL. Rat study: Meloxciam/TA. Zoopharm Bulletin.
4. Maddison JE. 2007. Cats and NSAIDs- what are the issues? Irish Veterinary Journal. 60(3): 174.
5. Seymour TL, Adams SC, Felt SA, Jampachaisri K, Yeomans DC, Pacharinsak C. 2016. Post-operative analgesia due to sustained-release buprenorphine, sustained-release meloxicam, and carprofen gel in a model of incisional pain in rats (Rattus norvegicus). JAALAS. 55(3):300.
6. Stewart LA, Imai DM, Beckett L, Li Y, Lloyd KC, Grimsrud KN. Injection-site Reactions to Sustained-release Meloxicam in Sprague-Dawley Rats. J Am Assoc Lab Anim Sci. 2020 Nov 1;59(6):726-731.