HUMAN SAFETY WARNINGS:
Not for use in humans. Keep out of the reach of children.

Adult Human User Safety while handling BupreLab-Rat in the laboratory:
Two trained staff for administration. BupreLab-Rat should only be handled and administered to rats by laboratory staff trained in the handling of potent opioids. To prevent human adverse reactions or abuse, at least 2 trained administrators should be present during injection of BupreLab-Rat.

Protective covering: To prevent direct contact of BupreLab-Rat with human skin or mucous membranes when handling the solution, protective clothing is recommended.

Mucous membrane or eye contact during administration: Direct contact of BupreLab-Rat with the eyes, oral or other mucous membranes of humans could result in absorption of buprenorphine and the potential for adverse reactions. If accidental eye, oral or other mucous membrane contact is made during administration, flush the area with water and contact a physician.

Skin contact during administration: If human skin is accidentally exposed to BupreLab-Rat, wash the exposed area with soap and water and contact a physician. Accidental exposure could result in absorption of buprenorphine and the potential for adverse reactions.

Drug Abuse, Addiction, and Diversion of Opioids:
Controlled Substance: BupreLab-Rat contains buprenorphine, a mu opioid partial agonist and Schedule III controlled substance with an abuse potential similar to other Schedule III opioids. BupreLab-Rat can be abused and is subject to misuse, abuse, addiction, and criminal diversion. BupreLab-Rat should be handled appropriately to minimize the risk of diversion, including restriction of access, the use of accounting procedures, and proper disposal methods, as appropriate to the laboratory setting and as required by law.

Abuse: Abuse of BupreLab-Rat poses a hazard of overdose and death. This risk is increased with concurrent abuse of alcohol and other substances including opioids and benzodiazepines.

Buprenorphine has been diverted for non-medical use into illicit channels of distribution. All people handling opioids require careful monitoring for signs of abuse. Drug abuse is the intentional non-therapeutic use of a prescription drug for its rewarding psychological or physiological effects. Abuse of opioids can occur in the absence of true addiction.

Storage and Disposal: BupreLab-Rat is a Class III opioid. Store in a locked, substantially constructed cabinet according to DEA and local controlled substance guidelines. Discard broken vials after 90 days. Any unused or expired vials must be destroyed by a DEA registered distributor, for further information, call 1-970-795-0950.

Physician information: BupreLab-Rat injectable solution is a mu opioid partial agonist (10 mg buprenorphine/mL). In the case of an emergency, provide the physician with the package insert. Naloxone may not be effective in reversing respiratory depression produced by buprenorphine. The onset of naloxone effect may be delayed by 10 minutes or more. Desacemorph hydrochloride has also been used as a respiratory stimulant.

PRECAUTIONS:
The safe use of BupreLab-Rat has not been evaluated in breastfeeding, pregnant, or lactating rats.

Buprenorphine, like other opioids, may cause sedation, respiratory depression, decreased heart rate, decreased gastric motility, low body temperature, corneal drying, reduction in food consumption, and reduction in body weight gain. These effects may be dependent on a number of factors including dose, sex or strain of rat, individual variation in drug sensitivity, individual health status, and other drugs being given concurrently. Rats should be monitored for signs of decreased cardiovascular and respiratory function when receiving BupreLab-Rat.

Before administering BupreLab-Rat, an opiate antagonist such as naloxone should be available in case reversal is required. Naloxone’s duration of action in most animals ranges from 45 minutes to 3 hours, so re-administration may be needed.

NOTE: Studies have reported that both buprenorphine and narcodepine are excised in the feces of rodents due to enterohepatic circulation of the drug. Based on these findings, treated rats and cages should be isolated to prevent excision of drug metabolites or its metabolites through coprophagy.1,2

ADVERSE REACTIONS:
During a laboratory study in which rats received a single subcutaneous injection of BupreLab-Rat at a dose of 1.2 mg/kg body weight, the only adverse reaction noted was skin irritation, including erythema and scabbing around the site of injection.1 Skin irritation occurred in rats that had leakage of BupreLab-Rat from the injection site immediately following removal of the needle. Skin irritation may be minimized by observing proper injection technique.

For technical assistance, or to report an adverse drug reaction, please call Wildlife Pharmaceuticals, Inc. at 970-795-0950.

Adverse drug reactions may also be reported to the FDA/CAM at 1-888-FDA-VETS or visit http://www.fda. gov/AnimalVeterinary/SafetyHealth.

CLINICAL PHARMACOLOGY:
Pharmacokinetic parameters of BupreLab-Rat were investigated in 6 female Sprague Dawley rats following a single subcutaneous injection of 1mg/kg bodyweight. Peak plasma concentrations of 3.38 ng/mL were reached at 4 hours, with linear decline thereafter to 0.09 ng/mL at 72 hours. The T1/2 of BupreLab-Rat was 11.48 hours.

STORAGE INFORMATION:
Store at controlled room temperature between 15°F and 30°C (59°F-86°F) in a facility consistent with appropriate Drug Enforcement Agency regulations regarding Schedule III Class drugs.

REFERENCES:

HOW SUPPLIED:
BupreLab-Rat is supplied in a 5 mL clear glass vial (1mg buprenorphine/mL).
Lot no:
Expiration date:
Store at controlled room temperature 15-30°C (59-86°F).

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

(buprenorphine extended-release injection)
5 mL
1 mg/mL

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Wildlife Pharmaceuticals, Inc.

Indications: For the control of post procedural pain in rats.

Directions: Read package insert completely before using.
The dosage in rats is a single subcutaneous injection of 1 to 1.5 mg/kg bodyweight.

Warning: Not for use in humans.
Keep out of the reach of children.
Store at controlled room temperature 15-30°C (59-86°F).

NOT APPROVED BY FDA
Legally marketed as an FDA Indexed Product under MIF-900-006.
Extra-label use is prohibited.
This product is not to be used in animals intended for use as food for human or food-producing animals.