Take the PAIN Out of Pain Management

An Ethical Imperative

The Essential Need for Effective Pain Management in Laboratory Mice and Rats

"The appropriate use of anesthetics, tranquilizers, analgesics, and nonpharmacologic interventions in research animals is an ethical and scientific imperative. ***Pain and distress are undesirable variables in most scientific research projects***, and if not relieved, can result in unacceptable animal welfare and invalid scientific outcomes."[1] (emphasis added)

—***American College of Laboratory Animal Medicine (ACLAM),*** *Position Statement on Pain and Distress in Research Animals*

Pharmaceutical Grade Medications Help Limit Risks–Use When Available

"The use of pharmaceutical grade chemicals and other substances ***ensures that toxic or unwanted side effects are not introduced into studies*** conducted with experimental animals. They should therefore be used, when available, for all animal-related procedures (USDA 1977b)."[2] (emphasis added)

—***NIH Guide for the Care and Use of Laboratory Animals***

Fidelis®
PHARMACEUTICALS

NEW Ethiqa XR™

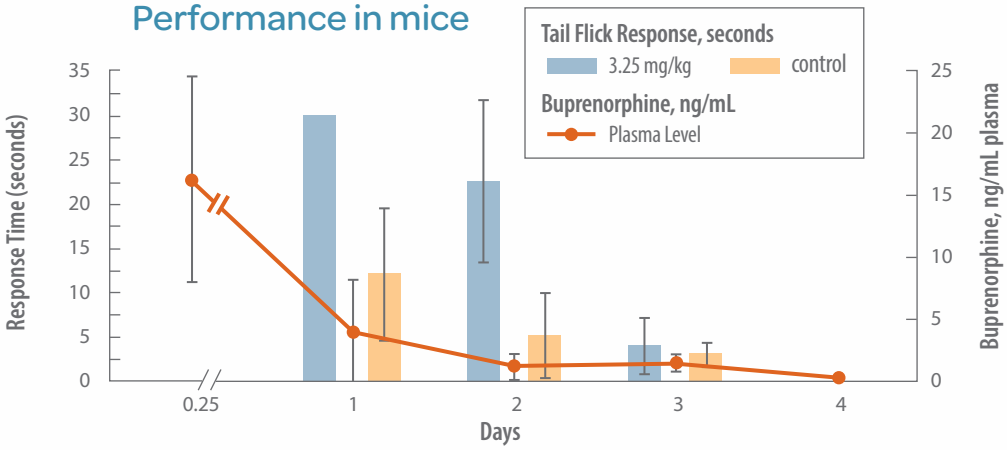
Confident Pharmaceutical Grade Quality[3]

The only FDA-indexed cGMP extended-release buprenorphine indicated for post-procedural pain management in mice and rats*

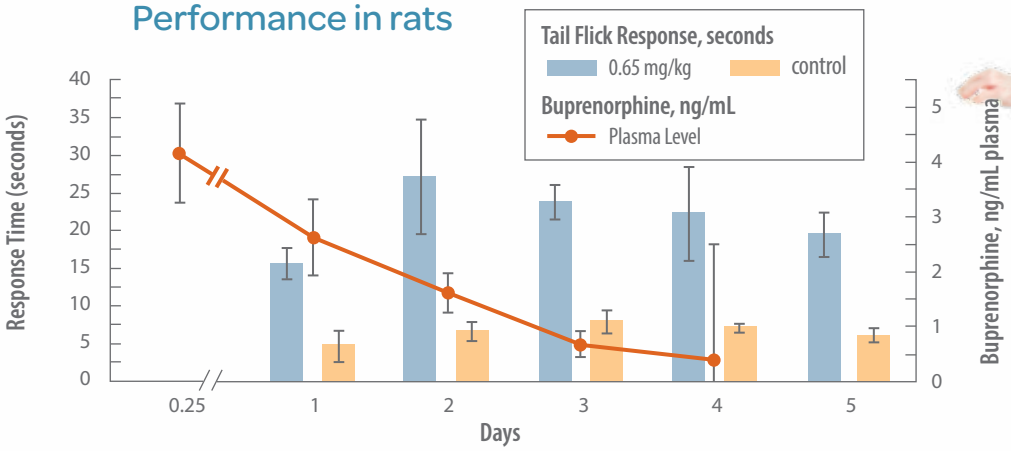
- Proven **long-acting, extended-release** technology
- Clinically significant blood levels were observed up to **72 hours** after subcutaneous administration in mice and rats with one injection
- One dose minimizes the inconvenience and animal stress of multiple injections

3 Days of Continuous Pharmaceutical Grade Relief

Performance in mice



Performance in rats



Only administer Ethiqa XR by subcutaneous injection. Ethiqa XR is not intended for intravenous, intra-arterial, intrathecal, intramuscular, or intra-peritoneal injection. Do not use on mice or rats with pre-existing respiratory deficiencies. Do not keep rats on wood chip-type bedding after administration of Ethiqa XR.

*** Please see Important Safety Information and Boxed Warning on reverse and accompanying Prescribing Information.**

Pure Peace of Mind with FDA-Indexed Safety[3]

Assurance of pharmaceutical grade product and safety and efficacy affirmed by FDA

- **Demonstrated safe** in extensive clinical studies at up to 5 times the indicated dose in mice and 10 times the indicated dose in rats following surgery
- **Dermal safety assurance**—no evidence of crusty injection-site skin lesions following administration
- **Less discomfort and stress** for lab animals and **less handling** by researchers

Get the Relief of Ethiqa XR™ Today

Visit ethiqaxr.com for additional information.

Ethiqa XR Specifications

Packaging	Multi-dose 3 mL vials
Buprenorphine concentration	1.3 mg/mL
Dosing—Mice	Single subcutaneous injection of 0.05 mL per 20-gram mouse (3.25 mg/kg body weight)
Dosing—Rats	Single subcutaneous injection of 0.1 mL per 200-gram rat (0.65 mg/kg body weight)
Dose Repetition	If needed, a single repeat dose may be administered after the initial dose
Syringe/Needle Size	Use a 0.5- or 1.0-mL syringe fitted with a 20- to 23-gauge needle for injections
Stability	Approved for 12-month shelf life
Storage	Store vial at 15° to 25°C (59° to 77°F) or refrigerated. Do not freeze. Store in a locked, substantially constructed cabinet according to DEA and local controlled substance guidelines.
Administration	Ethiqa XR should only be handled and administered by a veterinarian, veterinary technician or laboratory staff trained in the handling of potent opioids.

Learn more at **ethiqaxr.com**

Ethiqa XR™

(buprenorphine extended-release injectable suspension) 1.3 mg/mL

Get the Upper Hand in Post-Procedural Pain Relief

NEW Ethiqa XR™

Feel the Confidence of FDA-Indexed Pharmaceutical Grade

- FDA-indexed for use in mice and rats[3]
- Pharmaceutical grade[3]
- FDA-reviewed efficacy and safety[3]
  - Demonstrated 72-hour clinical analgesia
  - Single injection, extended release
- cGMP sterile; free of endotoxins[3]
- Favorable viscosity formulation for easy administration
- Simple to order with widespread availability from distributors
- Dermal safety—no evidence of crusty injection-site lesions[3]
- Improved animal welfare with minimal animal handling

Important Safety Information

The safety of Ethiqa XR has not been evaluated in pregnant, lactating, neonatal, or immune-compromised mice or rats. As with other opioids, buprenorphine may cause sedation, decreased blood pressure, decreased heart rate, decreased gastrointestinal mobility, and respiratory depression. Use caution with concomitant administration of Ethiqa XR with drugs that cause respiratory depression.

This formulation for mice and rats is legally marketed as an FDA-indexed product under MIF 900-014. Extra-label use is prohibited.

BOXED WARNING

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

Abuse Potential

This formulation contains buprenorphine, a high-concentration (1.3 mg/mL) opioid agonist and Schedule III controlled substance with an abuse potential similar to other Schedule III opioids. The high concentration may be a particular target for human abuse. Buprenorphine has opioid properties that in humans may lead to dependence of the morphine type. Abuse of buprenorphine may lead to low or moderate physical dependence or high psychological dependence. The risk of abuse by humans should be considered when storing, administering, and disposing. Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (suicidal depression). Because of human safety risks, this drug should be used only with veterinary supervision.

Do not dispense this formulation.

Life-Threatening Respiratory Depression

The concentration of buprenorphine is 1.3 mg/mL. Respiratory depression, including fatal cases, may occur with abuse of this formulation.

There are additive CNS depressant effects when used with alcohol, other opioids, or illicit drugs that cause central nervous system depression.

Because of the potential for adverse reactions associated with accidental injection, this formulation should only be administered by a veterinarian or laboratory staff trained in the handling of potent opioids.

Please see accompanying Prescribing Information for additional Important Safety Information.

References: 1. ACLAM Position Statement on Pain and Distress in Research Animals. *JAALAS*. November 2016;55(6): 821. Available at https://www.aclam.org/about/position-statements. Accessed July 23, 2019. **2.** Animal Care and Use Program. In: Guide for the Care and Use of Laboratory Animals. 8th ed. Washington, DC:The National Academies Press;2011:chap2,31. Available at: https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf. Accessed July 25, 2019. **3.** Data on file, Fidelis Pharmaceuticals, LLC.

An extended-release formulation from

Fidelis PHARMACEUTICALS

675 US Highway One, Suite B113, North Brunswick, NJ 08902
833-ETHIQAXR (833-384-4729)
Manufactured by AltaSciences, Harleysville, PA

Ethiqa XR™
(buprenorphine extended-release injectable suspension) 1.3 mg/mL