For the ethical treatment of laboratory mice and rats...

1 INJECTION. 72 HOURS OF CLINICAL ANALGESIA.

FDA-Indexed extended-release buprenorphine. Made in a CGMP-regulated facility.

- **Extended-release pain management**—a reliable option for a significant need
- **Safeguards animal welfare**—benefits biomedical research
- **Accurate dosing**—low viscosity enables small syringes and needles
- **Simple ordering**—available through conventional supply chain

Pharmaceutical grade. Indexed by FDA.

- **Confidence**—FDA-indexed for use in mice and rats
- **Quality**—produced under FDA's strict Current Good Manufacturing Practices (CGMPs)
- **Compliance**—comports with oversight agency directives

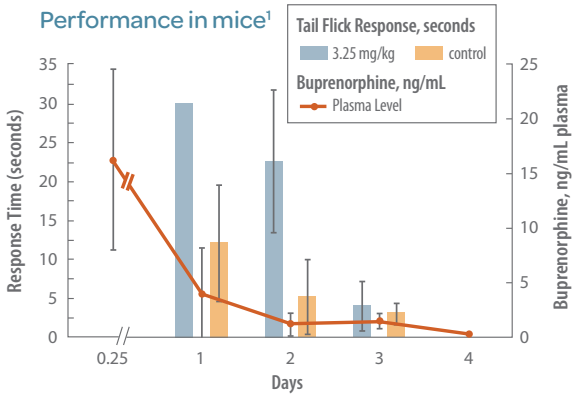
"Investigators are expected to use pharmaceutical-grade medications whenever they are available..."[2]

— Office of Laboratory Animal Welfare, National Institutes of Health

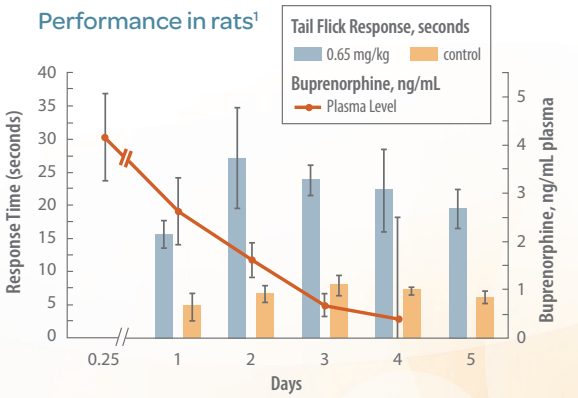
Long-acting technology. Extended-release pain relief.

- **Control**—manages risk of inadequate or insufficient analgesia
- **Efficiency**—minimizes animal subject handling
- **Convenience**—decreases administrative burden
- **User-friendliness**—low-viscosity formulation

Performance in mice[1]



Performance in rats[1]



An extended-release formulation from

Fidelis
PHARMACEUTICALS

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

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Description

An injectable suspension of extended-release buprenorphine. The sterile product contains cholesterol, glyceryl tristearate, and buprenorphine hydrochloride suspended in MCT oil.

Dosage and administration

How supplied	3.0 mL vials
Concentration of buprenorphine	1.3 mg/mL
Mouse dose (average dose)	3.25 mg/kg (0.05 mL per 20 g mouse)
Rat dose (average dose)	0.65 mg/kg (0.10 mL per 200 g rat)
Needle size	20- to 23-gauge (recommended due to viscosity of suspension)

Therapeutic levels are maintained for 72 hours after the initial dose. If needed, a single repeated dose may be administered 72 hours after the initial dose.

1. Use aseptic techniques to withdraw the dose into a disposable 0.5 or 1.0 mL syringe.
2. Insert the needle into the dorsal subcutaneous space created by the scruff hold and slowly inject entire dose. Following injection, an oily sheen may last 4-5 days but does not cause irritation or skin complications.
3. Do not keep rats on wood chip-type bedding after administration.
4. Do not return unused drug suspension from the syringe back into the vial.
5. Refer to the package insert for complete information prior to use.

Storage and handling

- The formulation is supplied in a multi-dose vial containing 3.0 mL of injectable suspension
- The vials should be stored between 15° and 25°C (59°–77°F) or refrigerated
- DO NOT FREEZE
- Once broached, the multi-dose vial should be discarded after 28 days

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

Important Safety Information

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. Data on file, Fidelis Pharmaceuticals, LLC. **2.** Clarke C. USDA regulations regarding non-pharmaceutical grade compounds in research. Office of Laboratory Animal Welfare, National Institutes of Health. March 2012. Available at: https://grants.nih.gov/grants/olaw/120301_NPG_slides.pdf. Accessed September 29, 2017.

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