

**For Immediate Release**

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## **Fidelis Animal Health, Inc. Announces Major Label Expansion for Ethiqaxr®**

*Ethiqaxr, an extended-release buprenorphine, adds captive rodents and laboratory rabbits to label for 72-hour control of post-procedural pain.*

**NORTH BRUNSWICK, NJ. November 5, 2024**—Fidelis Animal Health, Inc. has received notification from the Food and Drug Administration (FDA) that Ethiqaxr (buprenorphine extended-release injectable suspension) 1.3 mg/mL is now indicated for the control of post-procedural pain in captive rodents and laboratory rabbits. With Ethiqaxr, veterinarians have an FDA-indexed, pharmaceutical grade, cGMP extended-release buprenorphine for use in mice, naked mole rats, gerbils, hamsters, rats, chinchillas, guinea pigs, prairie dogs, ferrets, laboratory rabbits, and non-human primates.

“We are excited to bring these new indications to veterinarians in general and specialty practices, and in the research community. Ethiqaxr meets their high expectations for efficacy, safety, and quality, and makes it so much easier to comply with FDA GFI #256, which stresses the importance of using legal, FDA-indexed animal medications instead of compounded drugs for office stock and individual patient use<sup>1</sup>,” said Michael Wells, Board Chair and CEO.

“Ethiqaxr is an innovative form of buprenorphine that uses Fidelis Animal Health’s Fidelipid LAI™ technology, a patented lipid-based formulation that safely delivers 72 hours of clinical analgesia with just one subcutaneous injection<sup>2</sup>,” says Dr. Steven Leary, the company’s Chief Medical Officer. “It is manufactured in compliance with cGMP standards, meeting strict specifications to ensure consistency in quality and potency. Ethiqaxr is sterilized, with no harmful excipients, endotoxins, or microbial contamination.”

Since its launch to laboratory veterinarians in 2020, Ethiqaxr is currently being used in over five hundred institutions across the country, including those at the top ten pharmaceutical companies, many of the country’s elite academic institutions, hospital systems, and several government research facilities. Use is rapidly growing among practicing veterinarians who treat small mammals.

Ethiqaxr is easily and readily available from the major national veterinary distributors, including Covetrus, Patterson, MWI Animal Health and Midwest Veterinary Supply. For more information, visit [www.ethiqaxr.com](http://www.ethiqaxr.com).

## **IMPORTANT SAFETY INFORMATION**

### **For Captive Rodents, Ferrets, Laboratory Rabbits and Non-Human Primates:**

Only administer Ethiq XR<sup>®</sup> by subcutaneous injection. Ethiq XR is not intended for intravenous, intra-arterial, intrathecal, intramuscular, or intra-peritoneal injection. Do not use in animals with pre-existing respiratory compromise.

Death has been reported when non-steroidal anti-inflammatory drugs (NSAIDs such as meloxicam and carprofen) and Ethiq XR have been administered concomitantly in mice.

Do not house rats on wood chip-type bedding after administration of Ethiq XR. **Pica involving wood chip type bedding can be lethal.**

Ethiq XR may cause sedation, decreased blood pressure, decreased heart rate, decreased gastrointestinal mobility, and respiratory depression. Use caution with concomitant administration of Ethiq XR with drugs that cause respiratory depression. Animals should be monitored for signs of decreased cardiovascular and respiratory function when receiving Ethiq XR.

The safety of Ethiq XR has not been evaluated in pregnant, lactating, neonatal, or immune-compromised animals.

### **For Humans:**

Not for use in humans. Keep out of reach of children and pets.

**Ethiq XR contains buprenorphine, a Schedule III controlled substance with an abuse potential similar to other Schedule III opioids, which may lead to overdose and death.**

Ethiq XR should be handled appropriately to minimize the risk of misuse, abuse, addiction, and criminal 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.

Ethiq XR should only be handled and administered by a veterinarian, veterinarian technician, or laboratory staff trained in the handling of potent opioids. Wear protective clothing when administering Ethiq XR to avoid direct contact with human skin, eyes, oral, or other mucous membranes which could result in absorption of buprenorphine and adverse reactions.

*For more information, consult the Prescribing Information including the Boxed Warning.*

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## BOXED WARNING

### Abuse Potential

ETHIQA XR contains buprenorphine, an opioid that exposes humans to risks of misuse, abuse, and addiction, which can lead to overdose and death. Use of buprenorphine may lead to physical dependence. The risk of abuse by humans should be considered when storing, administering, and disposing of ETHIQA XR. Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drugs or alcohol) or mental illness (e.g., depression).

### Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with accidental exposure to or with misuse or abuse of ETHIQA XR. Monitor for respiratory depression if human exposure to buprenorphine occurs. Misuse or abuse of buprenorphine by swallowing, snorting, or injecting poses a significant risk of overdose and death.

### Accidental Exposure

Because of the potential for adverse reactions associated with accidental exposure, ETHIQA XR should only be administered by veterinarians, veterinary technicians, or laboratory staff who are trained in the handling of potent opioids. Accidental exposure to ETHIQA XR, especially in children, can result in a fatal overdose of buprenorphine.

**Risks From Concurrent Misuse or Abuse with Benzodiazepines or Other CNS Depressants** Concurrent misuse or abuse of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

See HUMAN SAFETY WARNINGS for detailed information.

**About Fidelis Animal Health:** Fidelis Animal Health is a commercial stage company offering exceptional expertise in the acquisition, development, and marketing of unique pharmaceutical formulations. The company is committed to leading the industry with developing and bringing to the market quality-driven therapeutics and additional innovations for all animals, small and large, using our proprietary extended- release technology.

**For more information about Fidelis Animal Health, please visit [www.FidelisAH.com](http://www.FidelisAH.com).**

1. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-256-compounding-animal-drugs-bulk-drug-substances>; accessed 3/14/2024.
2. [Ethiqa XR full prescribing information](#).