For Immediate Release

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Fidelis Animal Health Announces Ethiqa XR® Label Expansion

Ethiqa XR, an extended-release buprenorphine indicated for the control of post-procedural pain in mice, rats, ferrets and now FDA indexed in non-human primates (NHPs).

NORTH BRUNSWICK, NJ. April 2, 2024—Fidelis Animal Health has received notification from the Food and Drug Administration (FDA) that Ethiqa XR (buprenorphine extended-release injectable suspension) 1.3 mg/mL is now also indexed for the control of post-procedural pain in non-human primates (NHPs). With Ethiqa XR, veterinarians have an FDA-cleared, pharmaceutical grade, CGMP extended-release buprenorphine for use in four species: mice, rats, ferrets, and NHPs.

"We are excited to bring this new NHP indication to veterinarians. Now, these caregivers have a 3-day pain reliever that meets their high expectations for efficacy, safety, and quality. Ethiqa XR makes it so much easier to comply with the FDA's new Food, Drug and Cosmetic Act GFI #256, which stresses the importance of using legal, FDA-indexed animal medications instead of compounded drugs[1]," said Michael Wells, Board Chair and CEO.

Ethiqa XR is an innovative form of buprenorphine that uses Fidelis Animal Health's Fidelipid LAI™ technology, a patented lipid-based formulation that safely delivers up to 72 hours of clinical analgesia with just one subcutaneous injection. In the past, site reactions in NHPs have been reported to be quite common with other forms of buprenorphine[2]. "Fidelipid LAI technology has been shown to provide safe, 72-hour analgesia in non-human primates[2,3]," says Dr. Steven Leary, the company's Chief Medical Officer.

As an FDA-reviewed and accepted product for commercialization, Ethiqa XR is manufactured in compliance with cGMP standards, meeting strict specifications to ensure the quality and integrity of the finished product. Researchers and veterinarians do not need to be concerned about superpotency or sub-potency issues. Ethiqa XR is a sterile product with no harmful excipients, endotoxins, or microbial contamination. Ethiqa XR is easily and readily available from the major national veterinary distributors. For more information, visit www.ethiqaxr.com.

Since its launch in 2020, Ethiqa XR is currently being used in over four 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.

IMPORTANT SAFETY INFORMATION

For Mice, Rats, Ferrets, and Non-Human Primates:

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 in animals with pre-existing respiratory compromise.

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

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

Ethiqa XR 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. Animals should be monitored for signs of decreased cardiovascular and respiratory function when receiving Ethiqa XR.

The safety of Ethiqa 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.

Ethiqa 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.

Ethiqa 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.

Ethiqa 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 Ethiqa XR to avoid direct contact with human skin, eyes, oral, or other mucus 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.

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. Fabian NJ, Mannion AJ, Jamiel M, Anderson DJ, Rower JE, Reilly CA, Menegas W, Muthupalani S, Ta C, Fox JG, Kramer R, Haupt JL. Evaluation and comparison of pharmacokinetic profiles and safety of two extended-release buprenorphine formulations in common marmosets (Callithrix jacchus). Sci Rep. 2023 Jul 22;13(1):11864. doi: 10.1038/s41598-023-38973-2. PMID: 37481609; PMCID: PMC10363172.
3. Klein H, Levinson BL, Leary SL, Dobson G. A pharmacokinetic study of extended-release buprenorphine in cynomolgus monkeys (Macaca fasicularis). J Med Primatol. 2023 Dec;52(6):369-373. doi: 10.1111/jmp.12661. Epub 2023 Jul 11. PMID: 37432036.

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