For Immediate Release

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Fidelis Animal Health Announces Ethiqa XR® Label Expansion

Ethiqa XR, an extended-release buprenorphine indicated for post-procedural pain, is indexed for use in three species: Mice, rats - and now ferrets

NORTH BRUNSWICK, NJ. October 4, 2023—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 will now be indexed for the control of post-procedural pain in three different animal species. Previously Ethiqa XR was indicated for the control of post-procedural pain in mice and rats. This label expansion broadens the product indication, enabling it to be used with confidence in ferrets as well.

"This label expansion is important. It is the first planned expansion for Ethiqa XR, and we look forward to future indications for additional species. With our product, there's less need for animal handling, resulting in less stress, which significantly benefits the welfare of these animals." said Michael Wells, Chairman and CEO.

Ethiqa XR is an innovative formulation of buprenorphine that uses Fidelis Animal Health's Fidelipid LAI™ technology, a patented lipid-based formulation that delivers up to 72 hours of clinical analgesia with just one injection.

As an indexed product, 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 (no harmful excipients or microbial contamination).[1] Furthermore, Ethiqa XR adheres to key animal welfare guidelines, including the FDA Final Guidance on Compounding Animal Drugs from Bulk Drug Substances, NIH Pain Management Guidelines, and the ACLAM Position Statement on Pain and Distress in Research Animals.[2-4] Recently, FDA declined the listing of buprenorphine as a bulk drug substance for compounding office stock.

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Since its launch in 2020, Ethiqa XR is currently being used in over 350 institutions across the country, including those at the top 10 pharmaceutical companies, many of the country's elite academic institutions, and several government research branches. Ethiqa XR has been studied extensively in multiple species including mice, rats, and ferrets and several "off-label" species.

IMPORTANT SAFETY INFORMATION

For Mice, Rats, and Ferrets:

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.

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.

References: 1. Data on file at Fidelis Pharmaceuticals, North Brunswick, NJ; November 2021. **2.** Food and Drug Administration. Compounding Animal Drugs from Bulk Drug Substances: Guidance for Industry. 4/22/1022. Available at: https://www.fda.gov/media/132567/download. Accessed June 7, 2022. **3.** Guidelines for the use of non-pharmaceutical grade compounds in laboratory animals. National Institutes of Health, Office of Intramural Research, Office of Animal Care and Use Website. https://oacu.oir.nih.gov/sites/default/files/uploads/arac-guidelines/pharmaceutical_compounds.pdf. Accessed September 29, 2021. **4.** ACLAM Position Statement on Pain and Distress in Research Animals. *J Am Assoc Lab Anim Sci*. 2016;55(6):821. Available at https://www.aclam.org/about/position-statements. Updated December 8, 2016. Accessed September 29, 2021.

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