PRESS RELEASE

Guerbet

New indication in pediatric patients, including term neonates for Guerbet's half-dose GBCA, Elucirem™ (Gadopiclenol) Injection

Princeton, NJ, February 20, 2026 - Guerbet, a global specialist in contrast media and solutions for medical imaging, is pleased to announce that the U.S. Food and Drug Administration (FDA) has approved a labeling update for Elucirem™ (gadopiclenol) injection. The new indication includes approval for pediatric patients aged 0-2 years (including term neonates) for its macrocyclic high-relaxivity gadolinium-based contrast agent.

Guerbet's innovation, Elucirem™ is the first gadolinium-based contrast agent approved at half dose of gadolinium, and with the highest relaxivity, in comparison to other available gadolinium-based contrast agents (GBCA) [1]. Elucirem™ was approved by the FDA in September 2022 and by the EMA in December 2023. It is produced in France and also in the U.S. and is marketed by Guerbet in the following forms: vials and prefilled syringes.

In the U.S., Elucirem is indicated in adults and now in pediatric patients including term neonates, for use with magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in [2]:

- The central nervous system (brain, spine, and associated tissues)
- The body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system)

For these indications, an MRI examination with Elucirem™ requires half the conventional dose compared to that required with existing nonspecific contrast agents, thus addressing a concern of practitioners about gadolinium exposure.[3], [4], [5]

"*The new indication of Elucirem™ for pediatric patients, including term neonates, reflects our commitment to combining medical innovation and patient experience. Imaging departments will be able to perform contrast-enhanced MR imaging using half the conventional gadolinium dose, which is critical for patients, especially those requiring serial MRI examinations during their lifetime, as it reduces cumulative gadolinium exposure*", explains **Jim Patterson, General Manager North America**

"*Our pediatric patients are still developing and often vulnerable and we want to consider that with everything we do. One key asset of Elucirem™ is that, thanks to its higher relaxivity, we can get good image quality using only half the conventional gadolinium dose. That makes a real difference in terms of amount of gadolinium injected, especially for these young patients, without losing diagnostic accuracy.",* says **Dr. Azam Eghbal, Medical Director, Pediatric Radiology, Children's Hospital of Orange County**

ELUCIREM™ (gadopiclenol) injection Important Safety Information

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WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

Risk Associated with Intrathecal Use
Intrathecal administration of gadolinium-based contrast agents (GBCAs) can cause serious adverse reactions including death, coma, encephalopathy, and seizures.
ELUCIREM is not approved for intrathecal use.

Nephrogenic Systemic Fibrosis
GBCAs increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of ELUCIREM in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.
The risk for NSF appears highest among patients with:
- **Chronic, severe kidney disease (GFR <30 mL/min/1.73 m^2), or**
- **Acute kidney injury.**

Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (for example, age >60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.
For patients at highest risk for NSF, do not exceed the recommended ELUCIREM dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

Indications and Usage
ELUCIREM™ (gadopiclenol) injection is indicated in adult and pediatric patients, including term neonates for use with magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in the central nervous system (brain, spine, and associated tissues), and the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system).

Contraindications
Contraindicated in patients with history of hypersensitivity reactions to ELUCIREM.

Warnings and Precautions
- **Risk Associated with Intrathecal Use**: Intrathecal administration of GBCAs can cause serious adverse reactions including death, coma, encephalopathy, and seizures. The safety and effectiveness of ELUCIREM have not been established with intrathecal use. ELUCIREM is not approved for intrathecal use.
- **Nephrogenic Systemic Fibrosis:** GBCAs increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of ELUCIREM among these patients unless the diagnostic information is essential and not available with non-contrast MRI or other modalities.
- **Hypersensitivity Reactions:** With GBCAs, serious hypersensitivity reactions have occurred. Before ELUCIREM administration, assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders.
- **Gadolinium Retention:** Gadolinium is retained in the body for months or years in several organs. While clinical consequences of gadolinium retention have not been established in patients with normal renal function, certain patients might be at higher risk. These include patients requiring multiple lifetime doses, pregnant and pediatric patients, and patients with inflammatory conditions. Minimize repetitive GBCA imaging studies, particularly closely spaced studies when possible.
- **Acute Kidney Injury:** In patients with chronically reduced renal function, acute kidney injury requiring dialysis has occurred with the use of GBCAs.
- **Extravasation and Injection Site Reactions:** Injection site pain have been reported in the clinical studies with ELUCIREM. Extravasation during ELUCIREM administration may result in tissue irritation. Ensure catheter and venous patency before the injection of ELUCIREM.
- **Interference with Visualization of Lesions Visible with Non-Contrast MRI**: As with any GBCA, ELUCIREM may impair the visualization of lesions seen on non-contrast MRI.

Adverse Reactions:
In clinical trials, the most frequent adverse reactions that occurred in > 0.2% of patients who received ELUCIREM included: injection site pain, headache, nausea, injection site warmth, injection site coldness, dizziness, localized swelling and erythema. Postmarketing Experience with use of ELUCIREM or other GBCAs: Acute pancreatitis, acute respiratory distress syndrome, pulmonary edema.

Use in Specific Populations

- **Pregnancy:** GBCAs cross the human placenta and result in fetal exposure.
- **Lactation:** There are no data on the presence of ELUCIREM in human milk, the effects on the breastfed infant, or the effects on milk production.
- **Pediatric Use:** The safety and effectiveness of ELUCIREM for use with MRI to detect and visualize lesions with abnormal vascularity have been established in pediatric patients including term neonates. The safety of ELUCIREM has not been established in preterm neonates.
- **Geriatric Use:** Elucirem is known to be substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function.
- **Renal Impairment:** Avoid use of GBCAs among patients with renal impairment unless the diagnostic information is essential and not available with non-contrast MRI or other modalities

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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Please see the full Prescribing Information, including the Medication Guide, for additional important safety information.

About Guerbet

At Guerbet, we build lasting relationships to enable better living. This is our Purpose. We are a global leader in medical imaging, offering a comprehensive range of pharmaceutical products, medical devices, and digital and AI solutions for diagnostic and interventional imaging.Pioneers in contrast agents for 99 years, with 2,905 employees worldwide, we continuously innovate and dedicate 9% of our revenue to Research & Development across four centers in France and the United States. Guerbet (GBT) is listed on Euronext Paris, Compartment B, and achieved €841 million in revenue in 2024. For more information, please visit www.guerbet.com.

About Gadopiclenol

Gadopiclenol, initially invented by Guerbet, with the subsequent contribution of intellectual property held by Bracco, is a gadolinium-based macrocyclic contrast agent (GBCA) with high relaxivity. The efficacy and safety of Gadopiclenol have been evaluated in MRI to detect and visualize lesions with abnormal vascularity in: central nervous system, head and neck, thorax, abdomen, pelvis and musculoskeletal system.

Please click here for full Prescribing Information.

About the Guerbet / Bracco Imaging collaboration

Bracco Imaging and Guerbet in December 2021 entered a worldwide collaboration on Gadopiclenol manufacturing and research and development activities. Gadopiclenol will be commercialized independently under separate brands. Both Guerbet and Bracco Imaging each own valuable intellectual property on Gadopiclenol.

The strategic collaboration is expected to accelerate access to Gadopiclenol and deliver innovation, as well as better care to patients and caregivers alike.

1 GBCA: Gadolinium-Based Contrast Agent

2 Elucirem™ (Gadopiclenol) Prescribing information.

3 Robic C et al. Invest Radiol. 2019;54(8):475-484.

4 PRAC, European Medicines Agency, 2017

5 FDA Drug Safety Communication, 2017

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