



American Regent® Launches Gvoke VialDx™ (glucagon injection)

First concentrated, ready-to-dilute liquid glucagon available for diagnostic procedures



Shirley, NY – August 27, 2025: American Regent, Inc.® is pleased to announce the commercial launch and availability of Gvoke VialDx™ (glucagon injection).

Gvoke VialDx (glucagon injection) is a gastrointestinal motility inhibitor indicated for intravenous use as a diagnostic aid during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract in adult patients.

The launch of Gvoke VialDx is the result of a partnership between American Regent and Xeris Pharmaceuticals, Inc. Under the terms of the agreement, Xeris will be responsible for product supply, and American Regent will be responsible for the commercialization of Gvoke VialDx in the U.S.

Joann Gioia, Vice President and Chief Commercial Officer at American Regent, said, “We are eager to bring our commercial expertise in the hospital and acute care setting to our partnership with Xeris and contribute to the success of Gvoke VialDx. The addition of Gvoke VialDx to our portfolio aligns perfectly with our mission to provide patients with the essential medicines they need.”

“We’re proud to mark the commercial launch of Gvoke VialDx in partnership with American Regent. Gvoke VialDx is the first liquid glucagon available for use as a diagnostic aid and provides an important new option for hospitals and clinics. American Regent is a natural partner to commercialize Gvoke VialDx given their longstanding reputation as a leading provider of high-quality sterile injectable products,” said Kevin McCulloch, President and COO of Xeris.

Gvoke VialDx will be available as a 1-count, or 10-count package of 1 mg per 0.2 mL single-dose vials and is available for immediate shipment. Customers can order the product through their wholesaler, distributor, or by contacting the American Regent Customer Support Group at 1-800-645-1706.

Please see the Important Safety Information below. To view the Full Prescribing Information, please [click here](#). For additional information on Gvoke VialDx, please visit www.americanregent.com.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

GVOKE VialDx is contraindicated in patients with:

- Pheochromocytoma, because of the risk of substantial increase in blood pressure
- Insulinoma, because of the risk of hypoglycemia
- Prior hypersensitivity reaction to glucagon or to any of the excipients in GVOKE VialDx. Serious hypersensitivity reactions have been reported with glucagon and include anaphylactic shock with breathing difficulties and hypotension
- Glucagonoma, because of risk of hypoglycemia.

WARNINGS AND PRECAUTIONS

Substantial Increase in Blood Pressure in Patients with Pheochromocytoma

GVOKE VialDx is contraindicated in patients with pheochromocytoma because glucagon may stimulate the release of catecholamines from the tumor. If the patient develops a substantial increase in blood pressure and a previously

undiagnosed pheochromocytoma is suspected, 5 to 10 mg of phentolamine mesylate, administered intravenously, has been shown to be effective in lowering blood pressure.

Hypoglycemia in Patients with Insulinoma

In patients with insulinoma, administration of glucagon may produce an initial increase in blood glucose; however, glucagon administration may directly or indirectly (through an initial rise in blood glucose) stimulate exaggerated insulin release from an insulinoma and cause hypoglycemia. GVOKE VialDx is contraindicated in patients with insulinoma. If a patient develops symptoms of hypoglycemia after a dose of GVOKE VialDx, give glucose orally or intravenously.

Serious Hypersensitivity Reactions

Serious hypersensitivity reactions have been reported with glucagon products, including generalized rash, and in some cases anaphylactic shock with breathing difficulties and hypotension. Discontinue GVOKE VialDx if symptoms of serious hypersensitivity reactions occur. Advise patients and/or caregivers to seek immediate medical attention if the patient experiences any symptoms of serious hypersensitivity reactions. GVOKE VialDx is contraindicated in patients with a prior hypersensitivity reaction to glucagon, or any of the excipients in GVOKE VialDx.

Necrolytic Migratory Erythema (NME)

NME, a skin rash commonly associated with glucagonomas (glucagon-producing tumors) and characterized by scaly, pruritic erythematous plaques, bullae, and erosions, has been reported post marketing following continuous glucagon infusion. GVOKE VialDx is not approved for continuous infusion. NME lesions may affect the face, groin, perineum, and legs or be more widespread. In the reported cases, NME resolved with discontinuation of the glucagon, and treatment with corticosteroids was not effective. Should NME occur, consider whether the benefits of continuous glucagon infusion outweigh the risks.

Hyperglycemia With Intravenous Use as a Diagnostic Aid in Patients with Diabetes Mellitus

GVOKE VialDx in patients with diabetes mellitus may cause hyperglycemia. Monitor patients with diabetes for changes in blood glucose levels during treatment with GVOKE VialDx and treat hyperglycemia, if indicated.

Blood Pressure and Heart Rate Increase in Patients with Cardiac Disease When Used as a Diagnostic Aid

GVOKE VialDx may increase myocardial oxygen demand, blood pressure, and pulse rate, which may be life-threatening in patients with cardiac disease. Cardiac monitoring is recommended in patients with cardiac disease during use of GVOKE VialDx as a diagnostic aid, and an increase in blood pressure and pulse rate may require therapy.

Hypoglycemia in Patients with Glucagonoma

GVOKE VialDx administered to patients with glucagonoma may cause secondary hypoglycemia. GVOKE VialDx is contraindicated in patients with glucagonoma when used as a diagnostic aid. Test patients suspected of having glucagonoma for blood levels of glucagon prior to treatment and monitor for changes in blood glucose levels during treatment. If a patient develops symptoms of hypoglycemia after a dose of GVOKE VialDx, give glucose orally or intravenously.

ADVERSE REACTIONS

Clinical Trials Experience

The most common adverse reactions occurring in ≥5% of adult healthy volunteers who received 0.75 mg GVOKE VialDx intravenously were nausea, dysgeusia, headache, hot flush, and dizziness.

Postmarketing Experience

The following reactions have been identified during post-approval use of glucagon. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Necrolytic migratory erythema (NME) cases have been reported postmarketing in patients receiving continuous infusion of glucagon
- Hypoglycemia and hypoglycemic coma. Patients taking indomethacin may be more likely to experience hypoglycemia following glucagon administration

DRUG INTERACTIONS

Patients taking beta-blockers may have a transient increase in pulse and blood pressure when given GVOKE VialDx.

Insulin acts antagonistically to glucagon.

The concomitant use of anticholinergic drugs and GVOKE VialDx increases the risk of gastrointestinal adverse reactions due to additive effects on inhibition of gastrointestinal motility.

GVOKE VialDx may increase the anticoagulant effect of warfarin.

USE IN SPECIFIC POPULATIONS

Pediatric Use

Safety and effectiveness of GVOKE VialDx for use as a diagnostic aid during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract in pediatric patients have not been established.

Geriatric Use

Clinical studies of GVOKE VialDx did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger adult patients.

OVERDOSAGE

If overdosage occurs, the patient may experience nausea, vomiting, inhibition of GI tract motility, increase in blood pressure, and pulse rate. In case of suspected overdosing, serum potassium may decrease and should be monitored and corrected if needed. If the patient develops a dramatic increase in blood pressure, phentolamine mesylate has been shown to be effective in lowering blood pressure for the short time that control would be needed.

INDICATIONS AND USAGE

GVOKE VialDx is indicated for intravenous use as a diagnostic aid during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract in adult patients.

Please see [Full Prescribing Information](#).

You are encouraged to report Adverse Drug Events to Xeris Pharmaceuticals, Inc. at 1-877-937-4737, or to the FDA by visiting www.fda.gov/medwatch, or by calling 1-800-FDA-1088.

About American Regent

American Regent, Inc.®, a Daiichi Sankyo Group company, is an industry-leading injectable manufacturer. For over 50 years, American Regent has been developing, manufacturing, and supplying quality generic and branded injectables for healthcare providers. For more than 20 years, we have been a leader in IV iron therapy.

American Regent is committed to US-based manufacturing. To that end, over the last several years we have made significant investments in expanding and modernizing our manufacturing facilities in Ohio and New York. This expansion will nearly double our capacity and allow us to better serve our customers now and in the future.

Speed counts. Flexibility matters. Reliability and quality are paramount. Because patients should never have to wait for the medications they need.

For more information, please visit www.americanregent.com

About Xeris

Xeris Pharmaceuticals, Inc., a wholly owned subsidiary of Xeris Biopharma Holdings, Inc. (Nasdaq: XERS), is a fast-growing biopharmaceutical company committed to improving patient lives by developing and commercializing innovative products across a range of therapies. Xeris has three commercially available products: Recorlev®, for the treatment of endogenous

hypercortisolemia in patients with Cushing's syndrome; Gvoke®, a ready-to-use liquid glucagon for the treatment of severe hypoglycemia, and a gastrointestinal motility inhibitor when used during radiology exams as a diagnostic aid; and Keveyis®, a proven therapy for primary periodic paralysis. Xeris also has a pipeline of development programs led by XP-8121, a Phase 3-ready, once-weekly subcutaneous injection for hypothyroidism, as well as multiple early-stage programs leveraging Xeris' technology platforms, XeriSol® and XeriJect®, for its partners.

Xeris Biopharma Holdings, Inc. is headquartered in Chicago, IL. For more information, visit www.xerispharma.com, or follow on X, LinkedIn, or Instagram.

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