Endo Expands ADRENALIN® Ready-to-Use Premixed Bag Line with Three New Concentrations

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- *Endo adds ADRENALIN® premixed IV bags in concentrations of 2 mg, 5 mg, and 10 mg per 250 mL.*
- *Endo now offers ADRENALIN® premixed IV bags in five of the most used concentrations, including the 5 mg and 10 mg which align with ASHP's Standardize 4 Safety Initiative*
- *Endo's products are the first FDA-approved, commercially available manufacturer-prepared epinephrine premixed intravenous (IV) bag.*

MALVERN, Pa., Sept. 23, 2025 /PRNewswire/ -- Endo, a wholly-owned subsidiary of Mallinckrodt plc, announced today the launch of ADRENALIN® (epinephrine in 0.9% sodium chloride injection) premixed IV bags in three new concentrations: 2 mg/250 mL, 5 mg/250 mL (20 mcg/mL), and 10 mg/250 mL (40 mcg/mL).

With this launch, Endo expands its ADRENALIN® portfolio to include premixed IV bags in five concentrations: 2 mg, 4 mg, 5 mg, 8 mg, and 10 mg per 250 mL. The portfolio also includes ADRENALIN® (epinephrine injection, USP) in 1 mL single-dose and 30 mL multi-dose vials.

The 5 mg/250 mL and 10 mg/250 mL concentrations align with the American Society of Health-System Pharmacists (ASHP) Standardize 4 Safety Initiative, supporting efforts to reduce medication errors and enhance patient safety.

ADRENALIN® is the first FDA-approved, commercially available manufacturer-prepared epinephrine premixed IV bag, offering healthcare providers a ready-to-use solution that supports streamlined care delivery.

"We're proud to support hospital teams with ready-to-use medicines that help make care easier and more efficient," said Scott Sims, Senior Vice President and General Manager, Endo Injectable Solutions and Generics. "We're excited to grow our TruDelivery® portfolio and give providers more options to focus on what matters most–caring for patients."

Key product benefits include:

- No compounding or preparation required
- Single-port IV tubing to reduce the risk of inadvertent mixture
- 24-month shelf life at room temperature

ADRENALIN® premixed IV bag is indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.

The ADRENALIN® premixed IV bag is part of Endo's TruDelivery® product line and platform. Ready-to-use products streamline operations for hospitals by eliminating the need to prepare or transfer the product before patient administration. This may reduce waste and costs, optimize convenience and workflow, and reduce the chance for preparation error—all of which support quality patient care.

About ASHP and Standardize 4 Safety Initiative
ASHP, the largest association of pharmacy professionals in the U.S., received funding from the FDA's Safe Use Initiative to develop and implement national standardized concentrations for intravenous (IV) and oral liquid medications. This effort led to the creation of Standardize 4 Safety, the first national, interprofessional initiative aimed at reducing medication errors—especially during transitions of care.

Developed in collaboration with pharmacists, nurses, and physicians across the care continuum, the initiative provides standardized concentration lists for patients of all ages in settings from hospital to home. Hospitals and health systems are encouraged to adopt these lists to enhance safety and reduce errors. Additional lists are forthcoming, and professionals can register with ASHP to receive updates.

For more information, visit ashp.org.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypertension: Because individual response to epinephrine may vary significantly, monitor blood pressure frequently and titrate to avoid excessive increases in blood pressure. Patients receiving monoamine oxidase inhibitors (MAOI) or antidepressants of the triptyline or imipramine types may experience severe, prolonged hypertension when given epinephrine.

Pulmonary Edema: Epinephrine increases cardiac output and causes peripheral vasoconstriction, which may result in pulmonary edema.

Cardiac Arrhythmias and Ischemia: Epinephrine may induce cardiac arrhythmias and myocardial ischemia in patients, especially patients suffering from coronary artery disease, or cardiomyopathy.

Extravasation and Tissue Necrosis with Intravenous Infusion: Avoid extravasation of epinephrine into the tissues, to prevent local necrosis. When ADRENALIN® premixed IV bag is administered intravenously, check the infusion site frequently for free flow. Blanching along the course of the infused vein, sometimes without obvious extravasation, may be attributed to vasa vasorum constriction with increased permeability of the vein wall, permitting some leakage. This also may progress on rare occasions to superficial slough.

Hence, if blanching occurs, consider changing the infusion site at intervals to allow the effects of local vasoconstriction to subside. There is potential for gangrene in a lower extremity when infusions of catecholamine are given in an ankle vein.

Antidote for Extravasation Ischemia: To prevent sloughing and necrosis in areas in which extravasation has taken place, infiltrate the area with 10 mL to 15 mL of saline solution containing from 5 mg to 10 mg of phentolamine, an adrenergic blocking agent. Use a syringe with a fine hypodermic needle, with the solution being infiltrated liberally throughout the area, which is easily identified by its cold, hard, and pallid appearance. Sympathetic blockade with phentolamine causes immediate and conspicuous local hyperemic changes if the area is infiltrated within 12 hours.

Renal Impairment: Epinephrine constricts renal blood vessels, which may result in oliguria or renal impairment.

ADVERSE REACTIONS: Most common adverse reactions to systemically administered epinephrine are headache; anxiety; apprehensiveness; restlessness; tremor; weakness; dizziness; sweating; palpitations; pallor; peripheral coldness; nausea/vomiting; and/or respiratory difficulties. Arrhythmias, including fatal ventricular fibrillation, rapid rises in blood pressure producing cerebral hemorrhage, and angina have occurred.

DRUG INTERACTIONS:

- Drugs that counter the pressor effects of epinephrine include alpha blockers, vasodilators such as nitrates, diuretics, antihypertensives, and ergot alkaloids.
- Drugs that potentiate the effects of epinephrine include sympathomimetics, beta blockers, tricyclic antidepressants, MAO inhibitors, catechol-O-methyltransferase (COMT) inhibitors, clonidine, doxapram, oxytocin, levothyroxine sodium, and certain antihistamines.
- Drugs that increase the arrhythmogenic potential of epinephrine include beta blockers, cyclopropane and halogenated hydrocarbon anesthetics, antihistamines, exogenous thyroid hormones, diuretics, cardiac glycosides, and quinidine. Observe for development of cardiac arrhythmias.
- Potassium-depleting drugs, including corticosteroids, diuretics, and theophylline, potentiate the hypokalemic effects of epinephrine.

USE IN SPECIFIC POPULATIONS: Elderly patients and pregnant women may be at greater risk of developing adverse reactions when epinephrine is administered parenterally.

Click for Full Prescribing Information.

About Endo
Endo, a wholly owned subsidiary of Mallinckrodt plc, is a diversified therapeutics manufacturer boldly transforming insights into life-enhancing therapies. Our passionate team members collaborate to develop and deliver these essential medicines. Together, we are committed to helping everyone we serve live their best life. Learn more at www.endo.com or connect with us on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements
This release contains forward-looking statements, including with regard to product efficacy, potential treatments or indications, therapeutic outcomes or treatment responses, and any statements that refer to expected, estimated or anticipated future results or that do not relate solely to historical facts. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: the effects of each of Endo's and Mallinckrodt's recent emergences from bankruptcy; satisfaction of, and compliance with, regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; changes in market demand; issues with product quality, manufacturing or supply, or patient safety issues or adverse side effects or adverse reactions associated with our products; and other risks identified and described in more detail in the "Risk Factors" and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Endo's and Mallinckrodt's most recent Annual Reports on Form 10-K, Mallinckrodt's Registration Statement on Form S-4, as amended, and other filings with the Securities and Exchange Commission (SEC), all of which are available from the SEC's website (www.sec.gov) and Mallinckrodt's website (www.mallinckrodt.com). The forward-looking statements made herein speak only as of the date hereof and we do not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.

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