



FOR IMMEDIATE RELEASE

Media Contact

Eric Tatro, (224) 948-5353
media@baxter.com

Investor Contact

Clare Trachtman, (224) 948-3020

**BAXTER ANNOUNCES U.S. FDA APPROVAL AND LAUNCH OF READY-TO-USE
CARDIOVASCULAR MEDICINE NOREPINEPHRINE IN PREMIX FORMULATION**

- *First and only manufacturer-prepared premix formulation of norepinephrine available*
- *Offers variety of storage options under refrigeration and at room temperature, allowing drug to be placed closer to patient care settings*
- *Ready-to-use format means less chance of compounding errors and touch contamination associated with compounded drug formulations*

DEERFIELD, Ill., September 23, 2021 – Baxter International Inc. (NYSE:BAX), a global leader in sterile medication production and delivery, today announced the U.S. Food and Drug Administration (FDA) approval and commercial launch of premix Norepinephrine Bitartrate in 5% Dextrose Injection (norepinephrine). Norepinephrine is indicated to raise blood pressure in adult patients with severe, acute hypotension (low blood pressure). Baxter’s formulation of norepinephrine is the first and only manufacturer-prepared ready-to-use formulation and is available in 4 mg/250 mL (16 mcg/mL) and 8 mg/250 mL (32 mcg/mL) strengths. Please see Important Risk Information and link to full Prescribing Information below.

“In a critical care situation, speed, efficiency and safety are of the utmost priority,” said Heather Knight, general manager, U.S. Hospital Products, Baxter. “Our ready-to-use formulation of norepinephrine allows hospitals to store this medication closer to patient care settings like the emergency department, intensive care unit and surgical areas, letting them administer it faster while reducing the risk of compounding errors or touch contamination.”

Leading voices on guidelines for medication safety—including the Institute for Safe Medication Practices (ISMP) and American Society of Health-System Pharmacists (ASHP)—encourage



the use of “commercially prepared, premix parenteral products” versus products that are manually compounded, which is the process of combining different drug agents in specific quantities to fill individualized prescriptions. They also encourage the use of standard concentrations for safety and efficiency reasons.^{1,2}

The use of premixes, or ready-to-use formats of standard doses of commonly prescribed drugs, may offer operational efficiencies in the hospital pharmacy. Compounding a drug for patient use is a multi-step, manual process that requires oversight by pharmacy staff. Using a ready-to-use product can simplify the preparation process and may also help enhance patient safety by avoiding potential dosing errors that may occur when medications are compounded on site.

Norepinephrine is used to treat patients with life-threatening hypotension that can occur during certain medical conditions or surgical procedures as well as acute or emergent hypotension. Baxter’s formulation of norepinephrine has a shelf life of up to 21 months in a refrigerator, or up to 90 days at room temperature in overwrap and can be stored in automated dispensing cabinets at the point-of-care. Norepinephrine uses Baxter’s proprietary VIAFLO container technology, which is not made with natural rubber latex, PVC or DEHP.

Baxter ready-to-use drugs are manufactured in accordance with FDA regulations governing Current Good Manufacturing Practices (cGMP). Norepinephrine is currently available from Baxter in the United States.

About Baxter Pharmaceuticals

Baxter provides a wide range of high-value generic injectable medicines including difficult-to-manufacture oncology drugs and standard-dose, ready-to-use premixed injectable anti-infectives, analgesics and critical care medicines. Baxter has rapidly expanded its pharmaceuticals portfolio through recent acquisitions, strategic partnerships and internal development programs that will help increase access to essential medicines and advance pharmacy efficiency and patient care. Baxter is also the first and only company to offer all three of the most commonly used modern inhaled anesthetics for general anesthesia.

About Baxter

Every day, millions of patients and caregivers rely on Baxter’s leading portfolio of critical care, nutrition, renal, hospital and surgical products. For 90 years, we’ve been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers that make



it happen. With products, technologies and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on [Twitter](#), [LinkedIn](#) and [Facebook](#).

Rx Only. Please see accompanying full [Prescribing Information](#).

Important Risk Information

Indication

Norepinephrine Bitartrate in Dextrose Injection is indicated to raise blood pressure in adult patients with severe, acute hypotension.

Contraindications

- None

Warnings and Precautions

- **Tissue Ischemia:** Administration of **Norepinephrine Bitartrate in Dextrose Injection** to patients who are hypotensive from hypovolemia can result in severe peripheral and visceral vasoconstriction, decreased renal perfusion and reduced urine output, tissue hypoxia, lactic acidosis, and reduced systemic blood flow despite "normal" blood pressure. Address hypovolemia prior to initiating **Norepinephrine Bitartrate in Dextrose Injection**. Avoid use in patients with mesenteric or peripheral vascular thrombosis, as this may increase ischemia and extend the area of infarction.

Gangrene of the extremities has occurred in patients with occlusive or thrombotic vascular disease or who received prolonged or high dose infusions. Monitor for changes to the skin of the extremities in susceptible patients.

Extravasation of **Norepinephrine Bitartrate in Dextrose Injection** may cause necrosis and sloughing of surrounding tissue. To reduce the risk of extravasation, infuse into a large vein, check the infusion site frequently for free flow, and monitor for signs of extravasation. Avoid administration into the veins in the leg in elderly patients.

Emergency Treatment of Extravasation: Infiltrate the ischemic area as soon as possible, using a syringe with a fine hypodermic needle with 5 to 10 mg of phentolamine mesylate in 10 to 15 mL of 0.9% Sodium Chloride Injection in adults.

- **Hypotension after Abrupt Discontinuation:** Sudden cessation of the infusion rate may result in marked hypotension. When discontinuing the infusion, gradually reduce the **Norepinephrine Bitartrate in Dextrose Injection** infusion rate while expanding blood volume with intravenous fluids.

- **Cardiac Arrhythmias: Norepinephrine Bitartrate in Dextrose Injection** elevates intracellular calcium concentrations and may cause arrhythmias, particularly in the setting of hypoxia or hypercarbia. Perform continuous cardiac monitoring of patients with arrhythmias.
- Most common adverse reactions are hypertension and bradycardia.
- **Drug Interactions:**
Co-administration of **Norepinephrine Bitartrate in Dextrose Injection** with monoamine oxidase (MAO) inhibitors or other drugs with MAO-inhibiting properties (e.g., linezolid) or with tricyclic antidepressants (including amitriptyline, nortriptyline, protriptyline, clomipramine, desipramine, imipramine) can cause severe, prolonged hypertension.

Anti-diabetics: **Norepinephrine Bitartrate in Dextrose Injection** can decrease insulin sensitivity and raise blood glucose.

Concomitant use of **Norepinephrine Bitartrate in Dextrose Injection** with halogenated anesthetics (e.g., cyclopropane, desflurane, enflurane, isoflurane, and sevoflurane) may lead to ventricular tachycardia or ventricular fibrillation. Monitor cardiac rhythm in patients receiving concomitant halogenated anesthetics.

- Elderly patients may be at greater risk of developing adverse reactions.

This release includes forward-looking statements concerning ready-to-use norepinephrine, including expectations with regard to its availability in the U.S., the timing thereof, and potential benefits associated with Baxter's norepinephrine product and its use. 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: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; product quality, manufacturing or supply, or patient safety issues; changes in law and regulations; and other risks identified in Baxter's most recent filing on Form 10-K and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.

Baxter and VIAFLO are registered trademarks of Baxter International Inc.

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¹ Institute for Safe Medication Practices (ISMP). ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations. 2016. <http://www.ismp.org/guidelines/sterile-compounding>. Accessed August 13, 2021.

² Billstein-Leber M, Carrillo JD, Cassano AT, et al. ASHP Guidelines on Preventing Medication Errors in Hospitals. *Am J Health-Syst Pharm*. 2018;75;1493-1517.