



FOR IMMEDIATE RELEASE

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BAXTER ANNOUNCES U.S. FDA APPROVAL OF MYXREDLIN, THE FIRST AND ONLY READY-TO-USE INSULIN FOR IV INFUSION

- *Offers extended shelf life of 30 days at room temperature or 24 months refrigerated*
- *Novel, ready-to-use presentation eliminates need for admixing and batching*
- *Available in standardized concentration*

DEERFIELD, Ill., July 22, 2019 – 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 of **Myxredlin** (Insulin Human in 0.9% Sodium Chloride Injection). **Myxredlin** (pronounced mix-RED-lin) is the first and only ready-to-use insulin for IV infusion in the hospital and other acute care settings and features an extended shelf life of 30 days at room temperature (77 degrees F [25 degrees C]) or 24 months if refrigerated (36 degrees F to 46 degrees F [2 degrees C to 8 degrees C]) in the original carton to protect from light. **Myxredlin** is provided in a standardized concentration of 100 units/100 mL in a flexible plastic container. This innovative presentation helps ensure **Myxredlin** delivers a consistent, stable and predictable concentration with every administration, which is a key consideration for patient safety.

“Insulin is in the top five drug classes involved with medication errors, and more than 30 percent of those errors result in patient harm,”¹ said Robert Felicelli, president, Pharmaceuticals, Baxter. “When a patient requires intravenous insulin in the hospital, pharmacists have to manually admix insulin for treatment. With the launch of **Myxredlin**, clinicians will have access to a convenient, reliable presentation of ready-to-use insulin that can help ensure faster delivery to patients, streamlined workflow for pharmacists and nurses, and less waste for hospitals.”



Myxredlin is indicated for use as a short-acting human insulin to improve glycemic control in adults and pediatric patients with diabetes mellitus. **Myxredlin** is intended for use only in acute care settings under medical supervision.

Like many other medicines in Baxter's portfolio of premix and ready-to-use injectables, **Myxredlin** uses Baxter's proprietary **Galaxy** container technology. **Galaxy** is a non-PVC and non-DEHP system that enables premixed medicines to have a longer shelf life when stored at room temperature. Premixed and ready-to-use formats of standard doses of commonly prescribed drugs offer efficiencies for hospitals by simplifying the preparation process. Premixes and ready-to-use formulations may also enhance patient safety by helping to avoid potential errors or potential contamination that may occur when medications are admixed or compounded, the process of combining different drug agents in specific quantities to fill individualized prescriptions.

Baxter premix and ready-to-use drugs are formulated to adhere to strict Current Good Manufacturing Practice (CGMP) regulations established and monitored by the FDA. **Myxredlin** is expected to be available from Baxter in the United States before the end of the year.

About Baxter Pharmaceuticals

Baxter provides a wide range of high-value generic injectable medicines that help treat some of the most pressing healthcare needs facing patients today, 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 more than 85 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 for MYXREDLIN

Indication

Myxredlin is a short-acting human insulin indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.

Contraindications

- During episodes of hypoglycemia
- Hypersensitivity to insulin human or any of the excipients in **Myxredlin**

Warnings and Precautions

- Administer **Myxredlin** intravenously ONLY under medical supervision with close monitoring of blood glucose and potassium levels. Hypokalemia may be life-threatening if not treated.
- Individualize dose based on metabolic needs, blood glucose monitoring results, and glycemic control goal. Dosage adjustments may be needed with changes in nutrition, renal, or hepatic function or during acute illness.
- Adverse reactions observed with insulin human injection include hypoglycemia, allergic reactions, weight gain and edema.
- Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs): Observe for signs and symptoms of heart failure; such as shortness of breath, swelling of your ankles or feet, or sudden weight gain.

Dosage and Administration

- Inspect **Myxredlin** visually before use. It should appear clear and colorless. Do not use **Myxredlin** if particulate matter or coloration is seen.
- Do not add supplementary medication or additives.
- Do not use in series connections.
- Do not shake or freeze. Discard unused portion.

*This release includes forward-looking statements concerning **Myxredlin**, including expectations with regard to its availability in the U.S., the time thereof, and potential benefits associated with Baxter's **Myxredlin** 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; issues related to 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, **Myxredlin** and **Galaxy** are registered trademarks of Baxter International Inc.

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¹ Top Medication Safety Errors of 2016. The American Journal of Pharmacy Benefits.

<https://www.ajpb.com/news/top-medication-safety-errors-of-2016>. Published December 9, 2016.

Accessed June 20, 2019.