FOR IMMEDIATE RELEASE

BAXTER EXPANDS PHARMACEUTICALS PORTFOLIO WITH NEW INJECTABLE PRODUCTS IN THE U.S.

- *Five new launches reinforce Baxter's focus on differentiated products and enhance the company's Pharmaceuticals portfolio in critical therapeutic areas*
- *Products feature ready-to-use formulations to help support patient safety and offer added convenience for healthcare professionals*

DEERFIELD, Ill., APRIL 11, 2024 — Baxter International Inc. (NYSE:BAX), a global leader in injectables, anesthesia and drug compounding, announced the continued expansion of its Pharmaceuticals portfolio with five injectable product launches in the U.S.

"These launches demonstrate Baxter's focus on differentiated products that address unmet patient needs in key therapeutic areas, including anti-infective and anti-hypotensive medications," said Alok Sonig, executive vice president and group president, Pharmaceuticals, at Baxter. "We are proud to offer important new options for our customers and look forward to continuing to bring new innovations to the market."

Product launches within Baxter's Pharmaceuticals portfolio in the U.S. include the following. For all products, please see full Indications, Important Risk Information and links to full Prescribing Information below.

- Norepinephrine Bitartrate in 5% Dextrose Injection in a new 16 mg/250 mL strength, which is indicated to raise blood pressure in adult patients with severe, acute hypotension. Baxter offers the first and only FDA-approved ready-to-use Norepinephrine in Dextrose, and now provides Norepinephrine in 4 mg/250 mL, 8 mg/250 mL and 16 mg/250 mL strengths.
- Vasopressin in 0.9% Sodium Chloride Injection, the first and only FDA-approved ready-to-use Vasopressin in a flexible container. Vasopressin uses Baxter's proprietary sterile, closed system container, which is collapsible and does not require a vented intravenous set.[1] Manufactured closed drug-delivery systems decrease the need for manual admixture and reduce the possibility of contamination.[2] Vasopressin

is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines. Baxter offers Vasopressin in 20 units/100 mL and 40 units/100 mL strengths.

- Vancomycin Injection, USP in 5% Dextrose in new 1.25 g/250 mL and 1.5 g/300 mL strengths. These launches are Baxter's first frozen ready-to-use offerings in 250 mL and 300 mL volumes. Vancomycin is indicated for serious or severe infections caused by susceptible strains of methicillin-resistant (β-lactam-resistant) staphylococci. Baxter now offers Vancomycin in 500 mg/100 mL, 750 mg/150 mL, 1 g/200 mL, 1.25 g/250 mL and 1.5 g/300 mL strengths.
- Ropivacaine Hydrochloride Injection, USP in a ready-to-use, single-dose infusion bag. Ropivacaine is indicated in adults to produce local or regional anesthesia for surgery and for acute pain management. Baxter offers Ropivacaine in 200 mg/100 mL and 400 mg/200 mL strengths.
- Regadenoson Injection pre-filled syringe, a coronary vasodilator that is commonly used in pharmacologic stress testing. Baxter offers Regadenoson in a 0.4 mg/5 mL strength.

Ready-to-use formats of standard concentrations of commonly prescribed drugs may offer operational efficiencies for healthcare providers. Compounding a drug for patient use is a multi-step, manual process that requires oversight by pharmacy staff. A ready-to-use product can simplify the preparation process and support patient safety by reducing the chance of contamination[2] and avoiding potential errors that may occur when medications are compounded.[3]

These newly launched products are now available for use in the U.S.

About Baxter

Every day, millions of patients, caregivers and healthcare providers rely on Baxter's leading portfolio of diagnostic, critical care, kidney care, nutrition, hospital and surgical products used across patient homes, hospitals, physician offices and other sites of care. For more than 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers who make it happen. With products, digital health solutions 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 X/Twitter, LinkedIn and Facebook.

Norepinephrine Bitartrate in 5% Dextrose Injection

Indications

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

Important Risk Information

- Contraindications: None.
- 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 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.
- Elderly Patients: May be at a greater risk of developing adverse reactions.
- Adverse Reactions: 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 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 may lead to ventricular tachycardia or ventricular fibrillation. Monitor cardiac rhythm in patients receiving concomitant halogenated anesthetics.

Please see accompanying full Prescribing Information for Norepinephrine Bitartrate in 5% Dextrose Injection.

Vasopressin in 0.9% Sodium Chloride Injection

Indications

Vasopressin in Sodium Chloride Injection is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines.

Important Risk Information

- Contraindications: Vasopressin in Sodium Chloride Injection is contraindicated in patients with a known allergy or hypersensitivity to 8-L-arginine vasopressin.
- Worsening Cardiac Function: A decrease in cardiac index may be observed with the use of vasopressin.
- Reversible Diabetes Insipidus: Patients may experience reversible diabetes insipidus, manifested by the development of polyuria, a dilute urine, and hypernatremia, after cessation of treatment with vasopressin. Monitor serum electrolytes, fluid status and urine output after vasopressin discontinuation. Some patients may require readministration of vasopressin or administration of desmopressin to correct fluid and electrolyte shifts.
- Adverse Reactions:
  - The most common adverse reactions include decreased cardiac output, bradycardia, tachyarrhythmias, hyponatremia and ischemia (coronary, mesenteric, skin, digital).
- Drug Interactions:
  - Pressor effects of catecholamines and Vasopressin in Sodium Chloride Injection are expected to be additive.
  - Indomethacin may prolong effects of Vasopressin in Sodium Chloride Injection.
  - Co-administration of ganglionic blockers or drugs causing SIADH (syndrome of inappropriate antidiuretic hormone secretion) may increase the pressor response.
  - Co-administration of drugs causing diabetes insipidus may decrease the pressor response.
- Pregnancy: May induce tonic uterine contractions that could threaten the continuation of pregnancy.

Please see accompanying full Prescribing Information for Vasopressin in 0.9% Sodium Chloride Injection.

Vancomycin Injection, USP in 5% Dextrose

Indications

Vancomycin is indicated for the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant (beta-lactam-resistant) staphylococci. It is indicated for penicillin-allergic patients, for patients who cannot receive or who have failed to respond to other drugs, and for infections caused by vancomycin-susceptible organisms that are resistant to other antimicrobial drugs.

Vancomycin is effective in the treatment of:

- Infective Endocarditis (staphylococcal endocarditis; endocarditis caused by *Streptococcus viridans* or *S. bovis*, alone or in combination with an aminoglycoside; endocarditis caused by enterococci (e.g., *E. faecalis*), only in combination with an aminoglycoside; diphtheroid endocarditis; early-onset prosthetic valve endocarditis caused by *S. epidermidis* or diphtheroids in combination with either rifampin, an aminoglycoside, or both)
- Septicemia
- Skin and Skin Structure Infections
- Bone Infections
- Lower Respiratory Tract Infections

To reduce the development of drug-resistant bacteria and maintain the effectiveness of vancomycin and other antibacterial drugs, vancomycin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Important Risk Information

- Contraindications: Vancomycin is contraindicated in patients with known hypersensitivity to this antibiotic. Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.
- Infusion Reactions: Rapid bolus administration (e.g., over several minutes) may be associated with exaggerated hypotension, including shock, and, rarely, cardiac arrest.

  During or soon after rapid infusion of vancomycin, patients may develop anaphylactoid reactions, including hypotension, wheezing, dyspnea, urticaria, or pruritus. Rapid infusion may also cause flushing of the upper body ("vancomycin infusion reaction") or pain and muscle spasm of the chest and back.

  Vancomycin should be administered over a period of not less than 60 minutes. Stopping the infusion usually results in prompt cessation of these reactions.
- Nephrotoxicity: Systemic vancomycin exposure may result in acute kidney injury (AKI). The risk of AKI increases as systemic exposure/serum levels increase. Monitor renal function in all patients; especially with underlying renal impairment, with co-morbidities, and receiving concomitant therapy with a known nephrotoxic drug.
- Ototoxicity: It may be transient or permanent. It has been reported mostly in patients who have been given excessive doses, who have an underlying hearing loss, or who are receiving

concomitant therapy with another ototoxic agent, such as an aminoglycoside. Vancomycin should be used with caution in patients with renal insufficiency.

- Severe Dermatologic Reactions: Toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP), and linear IgA bullous dermatosis (LABD) have been reported. Cutaneous signs or symptoms reported include skin rashes, mucosal lesions, and blisters. Discontinue vancomycin Injection at the first appearance of signs and symptoms of TEN, SJS, DRESS, AGEP, or LABD. Dosage of vancomycin must be adjusted for patients with renal dysfunction.
- *Clostridioides difficile* associated diarrhea (CDAD): May range in severity from mild diarrhea to fatal colitis. CDAD must be considered in all patients who present with diarrhea following antibiotic use. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.
- Hemorrhagic Occlusive Retinal Vasculitis: Including permanent loss of vision, occurred in patients receiving intracameral or intravitreal administration of vancomycin during or after cataract surgery. The safety and efficacy of vancomycin administered by the intracameral or the intravitreal route have not been established.
- Adverse Reactions: Not already mentioned above, patients have been reported to have neutropenia, phlebitis, drug fever, nausea, chills, and vasculitis in association with administration of vancomycin.
- Drug Interactions:
    - Anesthetic Agents: Concomitant administration of vancomycin and anesthetic agents has been associated with erythema and histamine-like flushing and anaphylactoid reactions.
    - Monitor renal function in patients receiving vancomycin and concurrent and/or sequential systemic or topical use of other potentially neurotoxic and/or nephrotoxic drugs, such as amphotericin B, aminoglycosides, bacitracin, polymyxin B, colistin, viomycin, or cisplatin.

Please see accompanying full Prescribing Information for Vancomycin Injection, USP.

Ropivacaine Hydrochloride Injection, USP

Indications

Ropivacaine Hydrochloride Injection is an amide local anesthetic indicated in adults for the production of local or regional anesthesia for surgery and for acute pain management.

- Surgical Anesthesia: epidural block for surgery including cesarean section; major nerve block; local infiltration.

- Acute Pain Management: epidural continuous infusion or intermittent bolus, e.g., postoperative or labor; local infiltration.

Important Risk Information

- Contraindications: Ropivacaine Hydrochloride Injection is contraindicated in patients with a known hypersensitivity to ropivacaine or to any local anesthetic agent of the amide type.

- General Warning: Delay in proper management of dose-related toxicity, underventilation, and/or altered sensitivity may lead to the development of acidosis, cardiac arrest and, possibly, death.

  The safe and effective use of local anesthetics depends on proper dosage, correct technique, adequate precautions, and readiness for emergencies.

  It is essential that aspiration for blood, or cerebrospinal fluid (where applicable), be done prior to injecting any local anesthetic, both the original dose and all subsequent doses, to avoid intravascular or subarachnoid injection.

- Unintended Intravenous Injection: In performing Ropivacaine Hydrochloride Injection blocks, unintended intravenous injection is possible and may result in cardiac arrhythmia or cardiac arrest. Ropivacaine hydrochloride injection should be administered in incremental doses. It is not recommended for emergency situations, where a fast onset of surgical anesthesia is necessary.

- Intra-Articular Infusions and Risk of Chondrolysis: Intra-articular infusions of local anesthetics may cause chondrolysis. Ropivacaine Hydrochloride Injection is not approved for this use.

- Risk of Methemoglobinemia: Patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended. Signs of methemoglobinemia may occur immediately or may be delayed some hours after exposure. Immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue ropivacaine hydrochloride injection and any other oxidizing agents.

- Central Nervous System Toxicity: Careful and constant monitoring of cardiovascular and respiratory vital signs and the patient's state of consciousness should be performed after each local anesthetic injection.

- Hepatic Disease: Because amide-type local anesthetics such as ropivacaine are metabolized by the liver, these drugs, especially repeat doses, should be used cautiously in patients with

hepatic disease. Patients with severe hepatic disease are at a greater risk of developing toxic plasma concentrations.

- Adverse Reactions: Most common adverse reactions (incidence ≥ 5%) are hypotension, nausea, vomiting, bradycardia, fever, pain, postoperative complications, anemia, paresthesia, headache, pruritus, and back pain.

- Drug Interactions:

    - Agents structurally related to amide-type local anesthetics: Concurrent use may cause additive effects.

Please see accompanying full Prescribing Information for Ropivacaine Hydrochloride Injection, USP.

Regadenoson Injection

Indications

Regadenoson injection is a pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress.

Important Risk Information

- Contraindications: Do not administer regadenoson injection to patients with: Second- or third-degree AV block, or Sinus node dysfunction, unless these patients have a functioning artificial pacemaker.
- Myocardial Ischemia: Fatal cardiac events have occurred. Avoid use in patients with symptoms or signs of acute myocardial ischemia, for example unstable angina or cardiovascular instability, who may be at greater risk. Cardiac resuscitation equipment and trained staff should be available before administration.
- Sinoatrial (SA) and Atrioventricular (AV) Nodal Block: Adenosine receptor agonists, including regadenoson injection, can depress the SA and AV nodes and may cause first-, second- or third-degree AV block, or sinus bradycardia.
- Atrial Fibrillation/Atrial Flutter: New-onset or recurrent atrial fibrillation with rapid ventricular response and atrial flutter have been reported.
- Hypersensitivity, Including Anaphylaxis: Anaphylaxis, angioedema, cardiac or respiratory arrest, respiratory distress, decreased oxygen saturation, hypotension, throat tightness, urticaria and rashes have occurred. Have personnel and resuscitative equipment immediately available.
- Hypotension: Adenosine receptor agonists, including regadenoson injection, induce vasodilation and hypotension. The risk of serious hypotension may be higher in patients with autonomic dysfunction, stenotic valvular heart disease, pericarditis or pericardial effusions, stenotic carotid artery disease with cerebrovascular insufficiency, or hypovolemia.

- Hypertension: Adenosine receptor agonists, including regadenoson injection, may induce clinically significant increases in blood pressure particularly in patients with a history of hypertension and when the MPI includes low level exercise.
- Bronchoconstriction: Adenosine receptor agonists, including regadenoson injection, may induce dyspnea, bronchoconstriction and respiratory compromise, especially in patients with chronic obstructive pulmonary disease (COPD) or asthma. Resuscitative measures should be available.
- Seizure: Regadenoson injection may lower the seizure threshold. New onset or recurrence of convulsive seizures has occurred. Some seizures are prolonged and require urgent anticonvulsive management. Methylxanthine use is not recommended in patients who experience a seizure in association with regadenoson injection.
- Cerebrovascular Accident (Stroke): Hemorrhagic and ischemic cerebrovascular accidents have occurred.
- Adverse Reactions: The most common (incidence ≥ 5%) adverse reactions to regadenoson injection are dyspnea, headache, flushing, chest discomfort, dizziness, angina pectoris, chest pain, and nausea.
- Drug Interactions:
    - Methylxanthines, e.g., caffeine, aminophylline and theophylline, interfere with the activity of regadenoson injection.
    - Aminophylline may be used to attenuate severe and/or persistent adverse reactions to regadenoson injection.
    - Dipyridamole may increase the activity of regadenoson injection. When possible, withhold dipyridamole for at least two days prior to regadenoson injection administration.

Please see accompanying full Prescribing Information for Regadenoson Injection.

This release includes forward-looking statements concerning Norepinephrine Bitartrate in 5% Dextrose Injection, Vasopressin in 0.9% Sodium Chloride Injection, *Vancomycin Injection, USP in 5% Dextrose, Ropivacaine Hydrochloride Injection, USP and Regadenoson Injection pre-filled syringe, including potential benefits associated with the use of these products. 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: demand for and market acceptance for new and existing products; product development risks; inability to create additional production capacity in a timely manner or the occurrence of other manufacturing or supply difficulties (including as a result of natural disasters, public health crises and epidemics/pandemics, regulatory actions or otherwise); 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 Form 10-Q and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.*

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[1] Baxter data on file

[2] Mercaldi CJ, Lanes S, Bradt J. Comparative risk of bloodstream infection in hospitalized patients receiving intravenous medication by open, point-of-care, or closed delivery systems. Am J Health-Syst Pharm. 2013;70:957-965.

[3] Billstein-Leber M, Carrillo CJD, Cassano AT, Moline K, Robertson JJ. ASHP Guidelines on Preventing Medication Errors in Hospitals. Am J Health Syst Pharm. 2018;75(19):1493-1517.

US-PH57-240005 (v1.0) 04/2024