

FOR IMMEDIATE RELEASE

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**BAXTER ANNOUNCES U.S. FDA APPROVAL AND COMMERCIAL LAUNCH OF  
READY-TO-USE CLINDAMYCIN INJECTION IN SALINE**

- *Only available premixed clindamycin injection in a saline presentation*
- *Provides additional access to commonly prescribed antibiotic in three standard doses*
- *Premixed presentation can help enhance patient safety and pharmacy efficiency*

**DEERFIELD, Ill., June 7, 2017** – 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 ready-to-use clindamycin injection in saline in three commonly prescribed formulations (300mg/50mL, 600mg/50mL, 900mg/50mL). Baxter made the announcement at the American Society of Health-System Pharmacists (ASHP) Summer Meetings, taking place this week.

Clindamycin is a widely prescribed antibiotic for serious infections caused by susceptible anaerobic bacteria and strains of streptococci, pneumococci and staphylococci when penicillin is inappropriate for a patient. For clinicians, clindamycin injection in saline provides an alternative to administer to patients for whom the use of dextrose is contraindicated or undesirable. Baxter's ready-to-use clindamycin injection in saline is now available to customers in the United States.

“The addition of clindamycin to Baxter’s portfolio of ready-to-use premixed medicines reinforces the company’s commitment to hospital pharmacies and to be a

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leader in the generic injectable pharmaceuticals space by providing high-quality, essential medicines that will benefit patients worldwide,” said Robert Felicelli, president, Pharmaceuticals, Baxter. “Only Baxter currently offers clindamycin in saline, making this important antibiotic suitable for use with a larger patient population.”

Baxter’s differentiated premix portfolio is made possible by a unique combination of proprietary technical capabilities in drug formulation, packaging and sterilization. Clindamycin injection in saline will use Baxter’s proprietary GALAXY container technology, a non-PVC and non-DEHP system that enables premixed medicines to have a longer shelf life when stored at room temperature.

Using premixed versions of standard doses of commonly prescribed drugs can help enhance patient safety by eliminating potential dosing errors that may occur when medications are compounded, a process that combines different drug agents in specific quantities to fill individualized prescriptions to meet a patient’s unique needs. Manufacturer-prepared premixed drugs are formulated to adhere to strict Current Good Manufacturing Practice (CGMP) regulations established and monitored by the FDA. Premixed medications also offer efficiencies for hospitals by simplifying the preparation process.

Clindamycin in saline is the third premix from Baxter to receive FDA approval since August 2015. Baxter remains committed to providing additional premixes in an effort to advance pharmacy efficiency and patient care.

**Baxter Announces U.S. FDA Approval and Commercial Launch of Ready-to-Use Clindamycin Injection in Saline – Page 3****INDICATIONS AND USAGE for Clindamycin in 0.9% Sodium Chloride (clindamycin injection)**

Clindamycin is a lincosamide antibacterial indicated for the treatment of the following:

- Serious infections caused by susceptible anaerobic bacteria.
- Infections Due to Susceptible Strains of Streptococci, Pneumococci and Staphylococci.
- Lower Respiratory Tract Infections.
- Skin and Skin Structure Infections.
- Gynecological Infections.
- Intra-abdominal Infections.
- Septicemia.
- Bone and Joint Infections.

**Limitation of use**

Since clindamycin does not diffuse adequately into the cerebrospinal fluid, Clindamycin in 0.9% Sodium Chloride Injection should not be used in the treatment of meningitis.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Clindamycin in 0.9% Sodium Chloride Injection and other antibacterial drugs, Clindamycin in 0.9% Sodium Chloride Injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

**IMPORTANT RISK INFORMATION for Clindamycin in 0.9% Sodium Chloride (clindamycin injection)**

**WARNING: CLOSTRIDIUM DIFFICILE-ASSOCIATED DIARRHEA (CDAD) and COLITIS**

See full prescribing information for complete boxed warning.

Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Clindamycin in 0.9% Sodium Chloride Injection and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

Because Clindamycin in 0.9% Sodium Chloride Injection therapy has been associated with severe colitis which may end fatally, it should be reserved for serious infections where less toxic antimicrobial agents are inappropriate. It should not be used in patients with nonbacterial infections such as most upper respiratory tract infections.

*C. difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy.

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- Clindamycin injection is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin.
- Anaphylactic shock and anaphylactic reactions have been reported.
- Elderly patients with associated severe illness may have a greater risk of developing adverse reactions from diarrhea.
- Clindamycin in 0.9% Sodium Chloride Injection products should be avoided in individuals with a history of gastrointestinal disease, particularly colitis.
- Clindamycin in 0.9% Sodium Chloride Injection should be avoided in atopic individuals.
- During prolonged therapy periodic liver and kidney function tests and blood counts should be performed.
- The use of Clindamycin in 0.9% Sodium Chloride Injection may result in overgrowth of non-susceptible organisms-particularly yeasts.
- Prescribing Clindamycin in 0.9% Sodium Chloride Injection in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.
- Most common adverse reactions: gastrointestinal (abdominal pain, nausea, vomiting) and hypersensitivity reactions (anaphylaxis, urticaria, skin rash).

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

**About Baxter**

Baxter provides a broad portfolio of essential renal and hospital products, including home, acute and in-center dialysis; sterile IV solutions; infusion systems and devices; parenteral nutrition; surgery products and anesthetics; and pharmacy automation, software and services. The company's global footprint and the critical nature of its products and services play a key role in expanding access to healthcare in emerging and developed countries. Baxter's employees worldwide are building upon the company's rich heritage of medical breakthroughs to advance the next generation of healthcare innovations that enable patient care.

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*This release includes forward-looking statements concerning clindamycin injection, including expectations with regard to its availability in the U.S. and benefits associated with 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.*

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