

Leucadia Pharmaceuticals Launches Calcitonin Salmon Injection

First-and-Only Generic to MIACALCIN® Injection Marks Fourth First Generic FDA Approval for Rapidly Growing Drug Maker

CARLSBAD, Calif. – [Leucadia Pharmaceuticals](#), a U.S. leader in generic injectables and the commercial arm of [Custopharm, Inc.](#), today announced the launch of its latest FDA-approved generic, Calcitonin Salmon Injection, USP, Synthetic. The injection is therapeutically equivalent to MIACALCIN®¹ and is indicated for the early treatment of hypercalcemic emergencies when a rapid decrease in serum calcium is required. Calcitonin Salmon Injection is also used to treat osteoporosis in postmenopausal women and to treat Paget’s disease.

It is AP rated, bar coded, does not contain natural rubber latex and is provided as a sterile solution for subcutaneous or intramuscular injection.

“This is Leucadia’s fourth FDA approval for a first generic injectable in less than two years,” said Dr. William Larkins, Chief Executive Officer of Leucadia Pharmaceuticals. “Calcitonin Salmon Injection, USP once again demonstrates Leucadia’s commitment to the development and launch of critically needed, lower cost therapies in the generic injectables market.”

Leucadia Pharmaceuticals’ Calcitonin Salmon Injection, USP, Synthetic FDA approval includes a Competitive Generic Therapy (“CGT”) designation. Leucadia is the first approved applicant for CGT designation and is eligible for 180 days of market exclusivity which begins with the commercial marketing of the product.

Leucadia’s first-and-only FDA-approved products also include the novel generic to the antineoplastic agent VALSTAR®² (valrubicin) Sterile Solution for Intravesical Instillation which is indicated for patients whose CIS bladder cancer does not respond to Bacillus Calmette-Guerin treatment and who cannot have surgery to remove the bladder and Sodium Tetradecyl Sulfate (STS) Injection generic which is therapeutically equivalent to SOTRADECOL®³ and is used to treat small varicose veins of the lower legs.

Among the company’s other recent product additions are Acetaminophen Injection, 1000 mg/100 mL (10 mg/mL), an FDA-approved generic that is therapeutically equivalent to OFIRMEV®⁴, indicated for the management of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics and reduction of fever, Icatibant Injection, an FDA-approved generic used to treat hereditary angioedema (HAE) attacks of the throat (laryngeal attack) and Dihydroergotamine Mesylate Nasal Spray, which is therapeutically equivalent to MIGRANAL®⁵ and used for acute treatment of migraine headaches with or without aura.

¹ MIACALCIN® is a registered trademark of Mylan Pharma Group, Ltd.

² VALSTAR® is a registered trademark of Endo Pharmaceuticals

³ SOTRADECOL® is a registered trademark of Mylan Pharma Group, Ltd.

⁴ OFIRMEV® is a registered trademark of Mallinckrodt Pharmaceuticals

⁵ MIGRANAL® is a trademark of Bausch Health Companies Inc. or its affiliates

About Leucadia Pharmaceuticals

Leucadia Pharmaceuticals is a leader in the generic injectables market. We invest heavily in new product development while also pursuing partnerships and product acquisitions. Our goal is to provide important new generic injectable products to the acute and specialty markets and to reach communities and conditions that are under-served. Leucadia's products include Calcitonin Salmon Injection, USP, Synthetic, Acetaminophen Injection, Dihydroergotamine Mesylate Nasal Spray, Icatibant Injection, Sodium Tetradecyl Sulfate (STS) Injection, 3%, Valrubicin Intravesical Solution, USP, Pentobarbital Sodium Injection, USP and Fludarabine Phosphate for Injection, USP. Leucadia Pharmaceuticals was established in 2017 as the commercial arm of Custopharm, Inc. and is associated with Water Street Healthcare Partners. For more information, please visit leucadiapharma.com.

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