

Glenmark Pharmaceuticals Receives U.S. FDA Approval for Progesterone Vaginal Inserts, 100 mg

Elmwood Park, New Jersey, April 09, 2026 – Glenmark Pharmaceuticals Limited (Glenmark) has received final approval from the United States Food & Drug Administration (U.S. FDA) for Progesterone Vaginal Inserts, 100 mg, determined by the FDA to be bioequivalent and therapeutically equivalent¹ to the reference listed drug (RLD), Endometrin^{®2} Vaginal Inserts, 100 mg of Ferring Pharmaceuticals Inc. [NDA 022057]. Glenmark's Progesterone Vaginal Inserts, 100 mg will be distributed in the U.S. by Glenmark Pharmaceuticals Inc., USA.

According to IQVIA[®] sales data for the 12-month period ending February 2026, the Endometrin[®] Vaginal Inserts, 100 mg market³ achieved annual sales of approximately \$59.2 million*.

Commenting on the launch, Marc Kikuchi, President & Business Head, North America said, “At Glenmark, we remain focused on expanding access to quality and affordable medicines while continuing to strengthen our portfolio in the U.S. This approval for Progesterone Vaginal Inserts, 100 mg marks an important addition to our business and reinforces our focus on addressing patient needs in women's healthcare.”

¹Glenmark's Progesterone Vaginal Inserts, 100 mg is only approved for the indication(s) listed in Glenmark's approved label.

²All brand names and trademarks are the property of their respective owners.

³Market includes brand and all available therapeutic equivalents. Note: IQVIA[®] data obtained by Glenmark is only available for all approved RLD indications. Glenmark's product is only approved for the indications listed in Glenmark's approved label and is not marketed for all RLD indications.

*IQVIA[®] National Sales Perspectives: Retail & Non-Retail, February 2026

About Glenmark Pharmaceuticals Limited

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is a global, research-led pharmaceutical company with a unique focus on innovation and accessibility. We pioneer transformative breakthrough therapies that aim to redefine treatment while expanding access to high-quality and affordable medicines for patients around the world. With 11 world-class manufacturing facilities across four continents, supported by six cutting-edge R&D centres, and a commercial footprint in 80+ countries, we deliver a diversified portfolio across branded, innovative, generics, and consumer health products, with a focus on respiratory, dermatology, and oncology. Scrip 100 positions Glenmark among the Top 100 biopharmaceutical companies globally by pharmaceutical sales for 2024. For more information, visit www.glenmarkpharma.com

Press Release

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