

Press Release

For Immediate Distribution

Glenmark receives ANDA approval for Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg (OTC)

Mahwah, New Jersey, USA and Mumbai, India, June 12, 2024: Glenmark Specialty SA (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg (OTC), determined by the FDA to be bioequivalent¹ to Nexium^{®2} 24 HR Delayed-Release Capsules, 20 mg (OTC), of Haleon U.S. Holdings LLC. Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg (OTC), will be distributed in the U.S. by Glenmark Therapeutics Inc., USA.

According to Nielsen[®] syndicated data for the latest 52 weeks period ending May 18, 2024, the Nexium[®] 24 HR Delayed-Release Capsules, 20 mg (OTC) market³ achieved annual sales of approximately \$259.2 million*.

Glenmark's current portfolio consists of 197 products authorized for distribution in the U.S. marketplace and 50 ANDA's pending approval with the U.S. FDA. In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.

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About Glenmark Pharmaceuticals Ltd.

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is a research-led, global pharmaceutical company, having a presence across Branded, Generics, and OTC segments; with a focus on therapeutic areas of respiratory, dermatology and oncology. The company has 11 world-class manufacturing facilities spread across 4 continents, and operations in over 80 countries. In Vivo/Scrip 100 positions Glenmark amongst the Top 100 Companies Ranked by R&D and Pharmaceutical Sales, 2022; while Generics Bulletin/In Vivo places it in the Top 50 Generics and Biosimilars Companies Ranked by Sales, 2022. Glenmark's Green House Gas (GHG) emission reduction targets have been approved in 2023 by the Science Based Target initiative (SBTi), making it only the second pharmaceutical company in India to achieve this. The organization has impacted more than 3 million lives over the last decade through its CSR interventions. For more information, visit www.glenmarkpharma.com. You can follow us on LinkedIn (Glenmark Pharmaceuticals) and Instagram ([glenmark_pharma](https://www.instagram.com/glenmark_pharma)).

For more information, please contact

Udaykumar Murthy | corpcomm@glenmarkpharma.com | +91 9960377617

References:

¹Glenmark's Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg (OTC) are only approved for the indications listed in Glenmark's approved drug facts label.

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

³Market includes brand and all available therapeutic equivalents

*Nielsen[®] NIQ Discover; Syndicated Data for Period Ending May 18, 2024