

Zydus launches Mirabegron Extended-Release Tablets in the US

Ahmedabad, India, 22 April 2024

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereafter referred to as “Zydus”) announces the launch of Mirabegron Extended-Release Tablets, 25 mg in the US market. The company had earlier received final approval from the United States Food and Drug Administration (USFDA) to market Mirabegron Extended-Release Tablets USP 25 mg and 50 mg (USRLD: Myrbetriq® Extended-Release Tablets). Zydus is among the first suppliers to launch the generic version of Mirabegron Extended-Release Tablets, USP 25 mg in the US market and is prepared to launch Mirabegron Extended-Release Tablets, 50mg imminently.

Mirabegron is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency. The drug will be manufactured at the group’s formulation manufacturing facility in Ahmedabad SEZ, India.

Speaking on the launch, CEO Americas, Dr. Punit Patel, said, "As one of the first suppliers, we are pleased with the launch of generic Mirabegron which will improve access and availability of the generic product for patients in the US market. This is a significant launch for us which will strengthen our growth plans in US market in the current fiscal."

Mirabegron Extended-Release Tablets USP 25mg and 50mg had annual sales of USD 2.42bn in the US (IQVIA MAT February 2024).

The group now has 393 approvals and has so far filed over 460* ANDAs since the commencement of the filing process in FY 2003-04.

About Zydus Group

Zydus Lifesciences Ltd. with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global lifesciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group has a significant presence in cancer related therapies and offers a wide range of solutions with cytotoxic, supportive & targeted drugs. The group employs over 26,000 people worldwide, including 1,400 scientists engaged in R & D, and is driven by its mission to unlock new possibilities in lifesciences through quality healthcare solutions that impact lives. The group aspires to transform lives through path-breaking discoveries.

For more information, visit <https://www.zyduslife.com/zyduslife/>

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(*as of 31st December 2023)



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