

Zydus receives final approval from the USFDA for Esomeprazole Magnesium for Delayed-Release Oral Suspension, 20 mg and 40 mg

Ahmedabad, India, 8 June, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereafter referred to as “Zydus”) has received final approval from the United States Food and Drug Administration (USFDA) for Esomeprazole Magnesium for Delayed-Release Oral Suspension, 20 mg and 40 mg (USRLD: Nexium Delayed-Release for Oral Suspension, 20 mg and 40 mg).

Esomeprazole is used to treat certain stomach and esophagus problems (such as acid reflux and ulcer). It works by decreasing the amount of acid your stomach makes. It relieves symptoms such as heartburn, difficulty swallowing, and cough. This medication helps heal acid damage to the stomach and esophagus, helps prevent ulcers and is expected to help prevent cancer of the esophagus. Esomeprazole belongs to a class of drugs known as proton pump inhibitors (PPIs). The product will be manufactured at the group’s formulation manufacturing facility in Moraiya, Ahmedabad (India).

Esomeprazole Magnesium for Delayed-Release Oral Suspension, 20 mg and 40 mg had annual sales of USD 42 mn in the United States (IQVIA MAT April 2023).

The group now has 370 approvals and has so far filed over 442* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st March 2023)



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