

Zydus receives final approval from USFDA for Prucalopride Tablets, 1 mg and 2 mg

Ahmedabad, India, - 08 August, 2025

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 Prucalopride Tablets, 1 mg and 2 mg (USRLD: Motegrity[®] Tablets, 1 mg and 2 mg).

Prucalopride is prescribed for chronic idiopathic constipation (CIC), a condition where the cause of constipation is unknown. It helps stimulate peristalsis, natural muscle contractions in the colon, to promote more regular bowel movements. Prucalopride tablets will be produced at Zydus Lifesciences Ltd (SEZ), Ahmedabad. Prucalopride tablets had annual sales of USD 186.8 mn in the United States (IQVIA MAT June 2025).

The group now has 422 approvals and has so far filed 483* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 31st July 2025)*



**PRESS
RELEASE**

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