

Zydus receives final approval from USFDA for Celecoxib Capsules, 50 mg, 100 mg, 200 mg, and 400 mg

Ahmedabad, India, 15 July, 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 Celecoxib Capsules, 50 mg, 100 mg, 200 mg, and 400 mg (USRLD: Celebrex[®] Capsules, 50 mg, 100 mg, 200 mg, and 400 mg).

Celecoxib is a nonsteroidal anti-inflammatory drug (NSAID). It works by reducing hormones that cause inflammation and pain in the body. It is used to treat pain or inflammation caused by many conditions such as arthritis, ankylosing spondylitis, and menstrual pain. It is also used to treat juvenile rheumatoid arthritis in children who are at least 2 years old. Celecoxib capsules will be produced at Zydus Lifesciences Ltd (SEZ), Ahmedabad. Celecoxib capsules had annual sales of USD 122.6 mn in the United States (IQVIA MAT May 2025).

The group now has 428 approvals and has so far filed 492* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 31st March 2025)*



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