Zydus Lifesciences receives USFDA approval for Diroximel Fumarate delayed-release capsules

The approval covers the treatment of relapsing forms of multiple sclerosis in adults, with production to take place at Zydus Lifesciences, SEZ

Zydus Lifesciences (including its subsidiaries and affiliates, hereafter referred to as “Zydus”) has received final approval from the United States Food and Drug Administration (USFDA) for Diroximel Fumarate delayed-release capsules, 231 mg (USRLD: Vumerity Delayed-Release Capsules, 231 mg).

Diroximel Fumarate delayed-release capsules, 231 mg, are indicated for the treatment of relapsing forms of multiple sclerosis (MS) in adults. The capsules will be produced at Zydus Lifesciences, SEZ.

According to IQVIA MAT data for September 2025, Diroximel Fumarate delayed-release capsules had annual sales of USD 999.4 million in the United States.

The group now has 426 approvals and has filed 487 abbreviated new drug applications (ANDAs) since the commencement of the filing process in FY 2003-04.

News Source:

https://www.expresspharma.in/amp/zydus-lifesciences-receives-usfda-approval-for-diroximel-fumarate-delayed-release-capsules