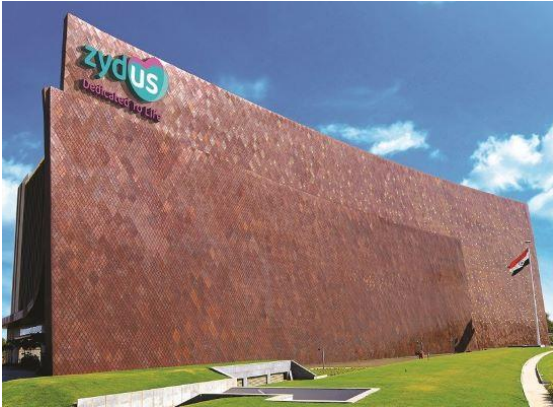


Zydus receives final approval from USFDA for Glatiramer Acetate Injection

Glatiramer Acetate is the generic version of Copaxone 20 mg/ml, 40 mg/ml, Single-Dose Prefilled Syringes



Zydus Lifesciences Limited has received final approval from the United States Food and Drug Administration (USFDA) for Glatiramer Acetate Injection, 20 mg/mL and 40 mg/mL, single-dose prefilled syringes.

Zydus' generic Glatiramer Acetate Injection is an FDA-approved, AP-rated substitutable generics of Copaxone® 20 mg/ml, 40 mg/ml and indicated for the treatment of relapsing forms of Multiple Sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Zydus' generic Glatiramer Acetate Injection, developed in collaboration with Chemi S.p.A., will be manufactured entirely in Europe.

"Zydus, together with Chemi, is proud to receive FDA approval for a substitutable generic version for this important therapy," said Dr Sharvil Patel, Managing Director, Zydus Lifesciences. "This approval underscores Zydus' leadership in bringing complex, differentiated generics to market, reinforcing our commitment to providing a comprehensive range of therapeutic choices for patients."

Dr. Francesco De Santis, Chairman of Italfarmaco Group said, "Together with our partner Zydus, we are proud to expand the availability of a cost-effective, high-quality generic treatment option for patients with relapsing-forms of Multiple Sclerosis."

Punit Patel, President & CEO Zydus Pharmaceuticals USA Inc., speaking on the development said, "The approval of Glatiramer Injection showcases our expertise in developing complex medications and reinforces our dedication to providing accessible, high-quality healthcare solutions."

Glatiramer Acetate Injection had annual sales of US\$ 719 million in the United States (IQVIA MAT Mar-2025). The group now has 426 approvals and has so far filed 492 ANDAs since the commencement of the filing process in FY 2003-04.

News Source:

<https://www.indianpharmapost.com/drug-approval/zydus-receives-final-approval-from-usfda-for-glatiramer-acetate-injection-17138>