Zydus receives final approval from USFDA for Amantadine extended-release capsules 68.5 mg and tentative approval for 137 mg

Eligible for 180 days of generic drug exclusivity for Amantadine extended-release capsules, 68.5 mg

Ahmedabad, India, 27 August, 2024

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) to market Amantadine extended-release capsules, 68.5 mg, and tentative approval for 137 mg (USRLD: Gocovri® (amantadine) extended-release capsules, 68.5 mg and 137 mg).

Amantadine extended-release capsules are indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. The drug will be manufactured at the group's formulation manufacturing facility in Ahmedabad SEZ - II, India.

This approval makes Zydus eligible for 180 days of exclusivity for Amantadine extended-release capsules, 68.5 mg.

The group now has 400 approvals and has so far filed over 465* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 30th June 2024)*

PRESS RELEASE

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