



August 27, 2024

BSE Limited

1st Floor, P J Towers,
Dalal Street,
Mumbai-400001

Code: 532321

National Stock Exchange of India Limited

Exchange Plaza, 5th Floor,
Plot No. C/1, G Block,
Bandra-Kurla Complex, Bandra (East),
Mumbai-400051

Code: Zyduslife

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated August 27, 2024, titled **“Zydus receives final approval from USFDA for Amantadine extended-release capsules 68.5 mg and tentative approval for 137 mg”**.

The contents of the press release give full details.

Please bring the aforesaid news to the notice of the members of the exchange and the investors' at large.

Thanking you,

Yours faithfully,

For, **ZYDUS LIFESCIENCES LIMITED**

DHAVAL N. SONI
COMPANY SECRETARY

Encl.: As above

Zydus Lifesciences Limited

Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle,
S. G. Highway, Ahmedabad-382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000
website : www.zyduslife.com | CIN : L24230GJ1995PLC025878



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**

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited

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