



Dedicated To Life

August 17, 2023

**BSE Limited**

1<sup>st</sup> Floor,  
P J Towers,  
Dalal Street,  
Mumbai-400001

**Code: 532321**

**National Stock Exchange of India Limited**

Exchange Plaza, 5<sup>th</sup> 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 17, 2023 titled "**Zydus receives final approval from the USFDA for Doxepin Tablets, 3 mg and 6 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** (formerly known as Cadila Healthcare 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](http://www.zyduslife.com) | CIN : L24230GJ1995PLC025878



## **Zydus receives final approval from the USFDA for Doxepin Tablets, 3 mg and 6 mg**

*Ahmedabad, India, 17 August, 2023*

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 Doxepin Tablets, 3 mg and 6 mg (USRLD: Silenor Tablets, 3 mg and 6 mg).

Doxepin is used to treat a certain sleep problem (insomnia). It is expected to help stay asleep longer and reduce the number of times a person wakes up during the night. Doxepin belongs to a class of drugs known as tricyclic antidepressants. The drug will be manufactured at the group’s formulation manufacturing facility at Moraiya.

Doxepin Tablets, 3 mg and 6 mg had annual sales of USD 43.4 mn in the United States (IQVIA MAT June 2023).

The group now has 376 approvals and has so far filed over 444\* ANDAs since the commencement of the filing process in FY 2003-04.

(\*as of 30<sup>th</sup> June 2023)

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**PRESS  
RELEASE**

For further information please contact :  
**The Corporate Communications Department**

**Zydus Lifesciences Limited**  
(formerly known as Cadila Healthcare Limited)

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