

Zydus receives final approval from the USFDA for Carbidopa and Levodopa Tablets USP, 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg

Ahmedabad, India, 6 April, 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) to manufacture and market Carbidopa and Levodopa Tablets USP, 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg (USRLD: Sinemet Tablets, 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg).

Carbidopa and Levodopa is used to treat symptoms of Parkinson's disease or Parkinson-like symptoms (such as shakiness, stiffness, difficulty moving). This medicine is also used to treat Parkinson symptoms caused by carbon monoxide, carbon monoxide poisoning or manganese intoxication. The product will be manufactured at the group’s formulation manufacturing facility in SEZ Ahmedabad, (India).

Carbidopa and Levodopa Tablets USP, 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg had annual sales of USD 75 mn in the United States (IQVIA MAT Dec. 2022).

The group now has 359 approvals and has so far filed over 440* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st December 2022)



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For further information please contact :
The Corporate Communications Department

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
CIN : L24230GJ1995PLC025878