Zydus Lifesciences gets tentative approval from USFDA for BP lowering drug

Azilsartan is indicated for the treatment of hypertension to lower blood pressure and reduce the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions, it added.

New Delhi: Zydus Lifesciences on Thursday said it has received tentative approval from the US health regulator to market its generic Azilsartan Medoxomil tablets used to treat high blood pressure. The tentative approval by the US Food and Drug Administration (USFDA) is for Azilsartan Medoxomil tablets of strengths 40 mg and 80 mg, Zydus Lifesciences said in a regulatory filing.

The drug will be manufactured at the group's formulation manufacturing facility in Ahmedabad SEZ - II, it added.

Azilsartan is indicated for the treatment of hypertension to lower blood pressure and reduce the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions, it added.

The medicine can be used either alone or in combination with other antihypertensive agents, the company said.

It had annual sales of USD 89 million in the US, the company said citing IQVIA March 2024 data.

News Source:

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