

India approves 2 weight loss drugs — Mounjaro and Zepbound: Here's all you need to know

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The committee has approved the import of single dose vials and pre-filled pens of the injectable drug in six different doses, ranging from 2.5 mg to 12.5 mg.

Indians can now avail the blockbuster weight loss and diabetes drug Tirzepatide — marketed as Mounjaro and Zepbound in the US and made by Eli Lilly — with the apex drug regulator's subject expert committee giving a go-ahead for its import and marketing. The final approval is expected to come from the Drug-Controller General of India based on this recommendation.

When this comes through, Indians will be able to access injectables of this class of drugs for the first time, bringing hope to those battling diabetes and obesity issues as studies show that these can reduce your body weight by up to 18 per cent. This widens the bouquet of availability and blunts the edge of the grey market. While the oral version of a weight loss drug made by Eli Lilly's Danish competitor Novo Nordisk — Semaglutide — has been approved and is available in India for diabetes management, its higher dose, injectable version meant for weight-loss isn't.

Mounjaro addresses diabetes more while Zepbound targets weight loss. Both will be available in a pre-filled pen and have to be injected subcutaneously (under the skin). In a statement to [The Indian Express](#), the makers said, "Eli Lilly has received marketing authorisation for Type 2 diabetes indication for Tirzepatide in India. Application for obesity indication is undergoing review by CDSCO. Launch timelines for India have not been confirmed yet." The committee has approved the import of single dose vials and pre-filled pens of the injectable drug in six different doses, ranging from 2.5 mg to 12.5 mg. This nod is based on two global clinical trials, which also included a significant number of Indians. In a trial of adults without type 2 diabetes, those on the highest dose of Tirzepatide lost an average of 18 per cent of their body weight in 72 weeks. And, in a trial among those with diabetes, participants lost an average of 12 per cent of their body weight.

WHY TIRZEPATIDE HAS AN EDGE OVER SEMAGLUTIDE

Semaglutide belongs to a class of drugs called GLP-1 receptor agonists, which lower serum glucose levels. Tirzepatide mimics both the GLP-1 hormone and the GIP hormone. The latter can trigger insulin creation and sensations of fullness, thereby increasing the chances of weight loss.

WILL THERE BE CHECKS AND BALANCES?

Eli Lilly has been asked to submit a protocol for a phase IV trial within three months. "The committee recommended grant of permission for import and marketing of Tirzepatide... subject to the condition that the firm should conduct Phase-IV clinical trial," according to the minutes of the meeting of the subject expert committee on endocrinology and metabolism held last month. A phase IV trial is important as it tracks people who have taken a new drug to study the side effects over time.

“The approval is based purely on objective criteria, including whether the trial shows the promised results, whether the trial is well-designed to study the objectives, whether there are enough participants from India and whether the impact in the Indian group is the same as the global group. Any global trial with 10 per cent Indian participants is likely to get approval. Such trials are well designed and do consider the Indian population as it is a significant market,” said one of the committee members on condition of anonymity.

“The only issue is that data is limited for a few years. We do not know the long-term impacts yet or for how long people with obesity have to continue to take it,” the expert added.

WHO CAN USE THE DRUGS?

The panel advised doctors to select the patients very carefully. “It should not be given to people with a history of pancreatic diseases, disorders of the endocrine systems, nausea and vomiting. The patients should also be asked to follow a diet and exercise first. The drug should be prescribed only when they are able to maintain the same weight level or bring it down by adhering to it,” the expert said.

ARE THE DRUGS EFFECTIVE?

Dr V Mohan, chairman, Dr V Mohan’s Diabetes Specialities Centre, Chennai, says the dosage should follow only after the patient has done lifestyle modifications and is still hovering around the body mass index (BMI) of 30. “These drugs may help knock off the weight initially but to sustain the weight loss, you will still need a diet, exercise and sleep discipline. Also the drugs need to be graded according to individual response as they do not work the same way for all,” says he, adding fats have a tendency to come back once you discontinue drug use.

CAN EVERYBODY AFFORD THESE DRUGS?

Although the committee’s brief is not to discuss pricing, these are expected to cost around Rs 15,000 a month. Long-term use would be a drain on the resources.

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