

DGCI gives approval to AstraZeneca for marketing diabetes drug

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Drug Controller General of India (DCGI) has given marketing authority to the drug firm AstraZeneca for Xigduo XR tablets used in treatment of adults with type 2 diabetes in India.

The product is indicated as an adjunct therapy to diet and exercise to improve glycemic control in adults with type 2 diabetes.

The company has not shared the price at which it would be selling the tablets. The drug has been approved in 61 countries, including the US, EU and Japan, and demonstrates an overall favourable benefit risk profile for treatment of patients with type 2 diabetes.

The diabetes drug will provide physicians and patients with an advanced treatment option that provides better glycemic control, potential weight loss and the reduced risk of hypoglycemia.

The product is approved with multiple dosage strengths of dapagliflozin and metformin hydrochloride extended-release, respectively, including 5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, and 10 mg/1,000 mg.

Through this tablet, the physicians will be offer a personalised and effective treatment option to manage the type 2 diabetes.