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Glenmark receives approval for combination drug for diabetes

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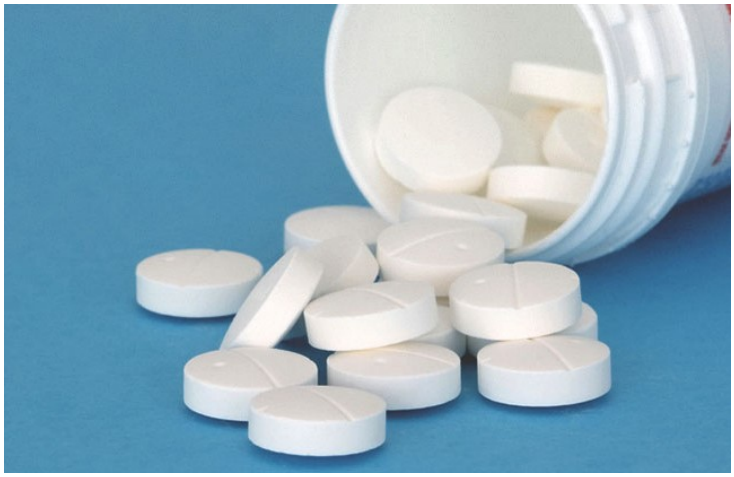
Remogliflozin is an innovative, patent-protected sodium glucose co-transporter-2 (SGLT2) inhibitor indicated in treatment of type-2 diabetes mellitus in adults



Glenmark Pharmaceuticals has received regulatory approval to market a combination of its novel, patent protected and globally-researched sodium glucose co-transporter-2 (SGLT2) inhibitor Remogliflozin etabonate (Remogliflozin) and Metformin Hydrochloride (Metformin) film coated tablets in India. The drug is indicated in the treatment of type-2 diabetes mellitus in adults. Glenmark will commercialize the product under the brand names ‘Remo-M’ and Remozen-M’.

Earlier in April 2019, Glenmark received regulatory approval for Remogliflozin etabonate 100 mg tablets, twice daily, after successfully completing Phase-3 clinical trials in which Remogliflozin demonstrated good efficacy and safety profile in a head-to-head comparison against Dapagliflozin. With this approval Glenmark became the first company in the world to launch the novel SGLT2 inhibitor Remogliflozin with India being the first country to get access to this innovative drug. Glenmark subsequently launched Remogliflozin in India under the brand names ‘Remo’ and ‘Remozen’.

Glenmark has now received regulatory approval for a combination of Remogliflozin and Metformin film coated tablets. The approved dosage strengths are 100 mg of Remogliflozin combined with either 500 mg or 1,000 mg of Metformin. This combination is indicated as an adjunct to diet and exercise to improve glycemic control in type-2 diabetes mellitus patients.

Sujesh Vasudevan, President, India Formulations, Middle East and Africa at Glenmark Pharmaceuticals said, “The approval for Remogliflozin and Metformin combination is a testament of our commitment towards revolutionizing diabetes management in India. Glenmark is a pioneer in providing access to the latest treatment options to diabetes patients in India. Earlier this year, we launched Remogliflozin with an aim to increase patients’ access to SGLT2 inhibitors as this class of drugs have proven benefits for effective diabetes management. As the prevalence of diabetes continues to rise rapidly, we are pleased to offer an additional treatment option to patients. This approval for combination of Remogliflozin and Metformin will only help us get closer to our goal of providing an effective, high quality and world-class treatment option and improving access to SGLT2 inhibitors for patients in India.”

The company had launched Remogliflozin as a mono-therapy, at a breakthrough price which is over 50% lower than the existing SGLT2 inhibitors available in India. Prior to the launch of Remogliflozin, the average per day therapy cost of SGLT2 inhibitors in India was about Rs. 55.