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Emcure to expand use of PoviztraÂ® for MASH indication following CDSCO approval

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PoviztraÂ® is manufactured and imported from Novo Nordisk's European manufacturing facility

Pune-based Emcure Pharmaceuticals has announced that Poviztra®, its co-marketed brand of innovator semaglutide (rDNA origin), will now be available for the treatment of non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH) in adults with moderate to advanced liver fibrosis (F2-F3), following the Central Drugs Standard Control Organization's (CDSCO) approval of Wegovy® for the indication.

The approval makes the innovator molecule from Novo Nordisk, the first and only GLP-1 receptor agonist approved in India for the treatment of the disease. It enables Emcure and its subsidiaries to offer the new indication through Poviztra®, expanding access to innovator semaglutide for patients living with a progressive liver disease that has long faced limited treatment options.

MASH develops when excess fat accumulation in the liver leads to chronic inflammation, fibrosis and progressive liver damage. Closely linked with obesity, type 2 diabetes and other metabolic disorders, the disease is often asymptomatic until advanced stages, making timely diagnosis and intervention critical.

The approval is supported by results from the global Phase III ESSENCE trial, in which semaglutide demonstrated resolution of steatohepatitis in 63% of patients and improvement in liver fibrosis in 37% of patients. One in three patients achieved both resolution of steatohepatitis and improvement in liver fibrosis, highlighting semaglutide's potential to address the underlying disease in addition to its established metabolic benefits.

Poviztra® contains innovator semaglutide (rDNA-origin) that has already established its role in chronic weight management in persons living with obesity and are overweight with co-morbid conditions (example Hypertension, Dyslipedemia, Type 2 Diabetes, etc). Poviztra® is also approved and marketed already for obese patients with established cardiovascular disease as well as more recently for management of adolescent obesity with pediatric patients above 12 years and above.