

CDSCO Expert Panel Backs Bajaj Healthcare's Novel Anti-Seizure Drug Cenobamate

New Delhi: Bajaj Healthcare Limited has received a recommendation from the Subject Expert Committee (SEC) (Neurology & Psychiatry) of the Central Drugs Standard Control Organisation (CDSCO) for the grant of permission to manufacture and market Cenobamate Tablets in strengths of 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg and 200 mg, making it the first company in India to secure such a recommendation for the product.

Cenobamate is a next-generation antiseizure medication developed for the treatment of partial-onset seizures in adults. The company stated that the medicine offers an innovative approach to seizure management, with clinical studies demonstrating significant seizure reduction and high seizure freedom rates in patients with inadequately controlled epilepsy, making it an important advancement in the evolving landscape of epilepsy treatment.

Commenting on the development, Anil Jain, Managing Director, Bajaj Healthcare Limited, said, "This approval represents a significant regulatory milestone for Bajaj Healthcare. It reflects the progress we have made in the development of Cenobamate Tablets and reinforces our commitment to expanding our portfolio of differentiated CNS therapies. We will continue to work closely with the regulatory authorities towards obtaining the necessary approvals and remain well-positioned to manufacture and commercialize the product, while further strengthening Bajaj Healthcare's position in the specialty pharmaceuticals segment."

The company stated that the SEC recommendation represents an important step in the regulatory pathway toward the manufacture and commercialization of Cenobamate Tablets in India. According to the Bajaj Healthcare investor release, the company is a leading manufacturer of Active Pharmaceutical Ingredients (APIs), pharmaceutical intermediates and formulations. Established in 1993, Bajaj Healthcare has built a strong reputation for manufacturing high-quality pharmaceutical products and nutraceuticals across multiple therapeutic segments. The company operates state-of-the-art manufacturing facilities designed to meet the requirements of both regulated and emerging markets and has a global presence serving customers across Europe, the United States, Australia, the Middle East and South America.

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