

Wockhardt gets CDSCO nod for Zaynich antibiotic

Synopsis

Wockhardt Ltd has secured approval from the CDSCO for its new antibiotic, Zaynich. This drug is developed in India and will be used to treat complicated urinary tract infections in adults. The approval follows successful clinical trials. Zaynich shows potential against drug-resistant bacteria. This marks a significant step in combating challenging infections.



Representative Image.

New Delhi: [Wockhardt Ltd](#) on Thursday said it has received approval from the Central Drugs Standard Control Organisation ([CDSCO](#)) for import and marketing of its indigenously discovered and developed [antibiotic, Zaynich](#) (Zidebactam/Cefepime) in India.

The approval is for the treatment of adult patients (18 years and above) with [complicated urinary tract infections](#) (cUTI), including pyelonephritis, as well as cases with concurrent Gram-negative bacteremia, [Wockhardt](#) Ltd said in a regulatory filing.

The nod by the drug regulator is supported by results from the pivotal ENHANCE-1 study, a multinational, randomised, double-blind Phase 3 clinical trial evaluating the efficacy and safety of Zaynich compared with meropenem in patients with cUTI, including pyelonephritis, the company said.

In recognition of its broad-spectrum potential, the Clinical and Laboratory Standards Institute has assigned Cefepime/Zidebactam an investigational susceptible breakpoint of 64 mg/L, supporting its potential to cover clinically important extensively drug-resistant (XDR) gram-negative pathogens in critically ill patients, it added.

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