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CDSCO approves AstraZeneca to import Sodium Zirconium Cyclosilicate for treatment of Hyperkalaemia in adult patients

06 March 2025 | News

Sodium Zirconium Cyclosilicate, an insoluble, non-absorbed sodium zirconium silicate, is administered as an oral suspension

AstraZeneca Pharma India Limited has received permission from the Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services, Government of India to import pharmaceutical formulations of new drug for sale or distribution for Sodium Zirconium Cyclosilicate (SZC) powder - oral suspension 5g and 10g.

This pioneering treatment is poised to significantly enhance the management of hyperkalaemia in adults, a condition characterised by elevated potassium levels that often accompanies cardiovascular, renal, and metabolic diseases.

Hyperkalaemia poses significant risks, primarily for patients with chronic kidney disease (CKD) and those on heart failure (HF) medication like renin-angiotensin-aldosterone system (RAAS) inhibitors, which can elevate potassium levels.

Alarmingly, hyperkalaemia prevalence is noted in 50% of CKD and 42% of chronic HF patients. To prevent hyperkalaemia recurrence, RAAS-inhibitor therapy often needs modification or discontinuation, potentially compromising cardio-renal outcomes and increasing mortality risk. In India, hyperkalaemia-related mortality stands at 22.2%. SZC stands to deliver a rapid, effective and generally well-tolerated treatment option to patients suffering from hyperkalaemia.

SZC, an insoluble, non-absorbed sodium zirconium silicate, is administered as an oral suspension. It is odourless, tasteless, and stable at room temperature. Clinical trials have demonstrated its effectiveness, with action onset in an hour and normalisation of potassium levels within 2.2 hours, achieved by 92% of patients within just 48 hours, sustained over a 12-month period.