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CDSCO approves AstraZeneca's anti-diabetic drug Dapagliflozin with additional indications

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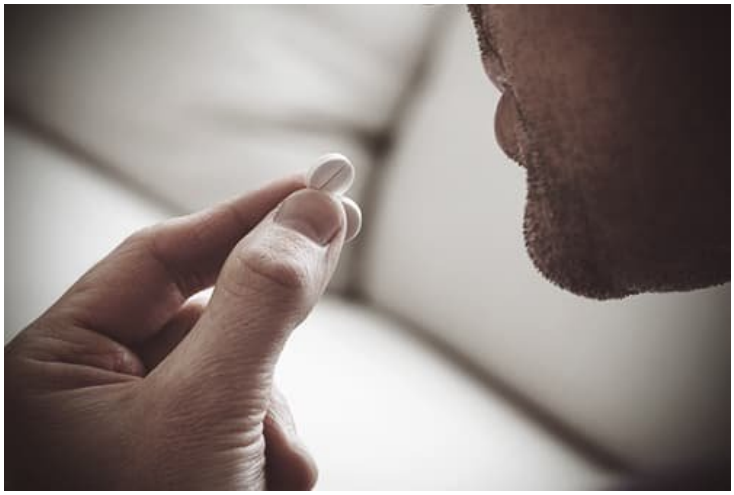
With additional indication for treatment of patients with Chronic Kidney Disease and Heart Failure



AstraZeneca India has received the Central Drugs Standard Control Organisation's (CDSCO) approval for their anti-diabetic drug Dapagliflozin in the treatment of adults with chronic kidney disease (CKD).

Dapagliflozin is the first and only anti-diabetic drug approved to significantly reduce the risk of sustained eGFR (estimated Glomerular Filtration Rate), cardiovascular deaths and hospitalisations due to heart failure in adults with progressive chronic kidney disease. This approval is applicable for both diabetic and non-diabetic CKD patients.

The approval is based on the consistent results from the DAPA-CKD study, where the indication has now been recommended in adults with Chronic Kidney Disease, up to an eGFR greater than or equal to 25 ml per min per 1.73 m^2. Below this, the initiation is currently not recommended, however patients may continue with their daily dose of 10mg orally to reduce the risk of eGFR decline, End Stage Kidney Disease (ESKD), cardiovascular deaths and heart failures. Earlier only up to CKD stage 3 patients could be initiated Dapagliflozin but with this approval physicians can initiate Dapagliflozin for a subset of CKD stage 4.

AstraZeneca's Dapagliflozin is an oral anti-diabetes drug which has shown increasing benefits in not only preventing heart failure but also in managing chronic kidney disease and heart failure with reduced ejection fraction irrespective of diabetes status.