Generic Name:
Tolvaptan
Trade Name:
Jynarque
Company:
Otsuka
Notes:

FDA has approved tolvaptan as the first drug treatment to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD), a genetic disease with consequences that can lead to dialysis or kidney transplantation.

ADPKD is a progressively debilitating and often painful disorder in which fluid-filled cysts develop in the kidneys over time. These cysts enlarge the kidneys and impair their ability to function normally, leading to kidney failure in most patients.

ADPKD is diagnosed in approximately 140,000 people in the United States and affects families across multiple generations, since a parent with ADPKD has a 50% chance of passing the disease on to each of their children.

Tolvaptan can cause serious and potentially fatal liver injury, and acute liver failure requiring liver transplantation has been reported. Tolvaptan has been associated with ALT and AST elevations, with infrequent cases of concomitant elevations in bilirubin-total.

To ensure the safety of patients taking tolvaptan, it is necessary to measure ALT, AST, and bilirubin before initiating treatment, at 2 weeks and 4 weeks after initiation, then monthly for 18 months and every 3 months thereafter, for as long as the patient is on tolvaptan treatment.

Because of the risks of serious liver injury, tolvaptan is available only through a restricted distribution program supported by a Risk Evaluation and Mitigation Strategy program approved by FDA.

Medication Monitor Categories:
Supplemental Approvals