

## Samsca® (tolvaptan) – First-time generic

- On May 20, 2020, Alkem/Ascend and <u>Apotex launched</u> <u>AB-rated</u> generic versions of Otsuka's <u>Samsca (tolvaptan)</u> 30 mg tablets.
- Samsca is approved for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and syndrome of inappropriate antidiuretic hormone.
- Tolvaptan is also available as brand 15 mg tablets (Samsca) and brand 15 mg and 30 mg tablets (Jynarque<sup>®</sup>).
  - Jynarque is approved to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease
- Samsca carries a boxed warning to initiate and re-initiate in a hospital and monitor serum sodium; and not for use for autosomal dominant polycystic kidney disease.



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