

FIRST TIME GENERIC APPROVAL

Brand Name	Samsca® Tablets
Generic Name	tolvaptan tablets
Drug Manufacturer	Apotex Inc., Alkem Laboratories Limited

New Drug Approval

Dosage form(s): 30 mg tablets

Therapeutic equivalent code: AB

FDA Approval Date: May 19, 2020

Indications for Use

tolvaptan tablets is indicated for:

- For the treatment of clinically significant hypervolemic and euvoletic hyponatremia.

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