



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Samsca™

Common Name: Tolvaptan

PDL Category: Vasopressins

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Vaprisol	N/A (Inpatient therapy)

Summary

Indications and Usage: Treatment of clinically significant hypervolemic and euvolemic hyponatremia, including patients with heart failure, cirrhosis, and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).¹

Mechanism of Action: Blocks the binding of vasopressin to the V2-receptors in the kidney, thus increasing the excretion of free water while not affecting the excretion of sodium and other electrolytes.¹

Dosage Forms: Tablets: 15mg, 30mg

Recommended Dosage: Samsca should be initiated and re-initiated in a hospital. The recommended starting dose is 15 mg once daily. Dosage may be increased at intervals ≥ 24 hr to 30 mg once daily, and to a maximum of 60 mg once daily as needed to raise serum sodium.¹

Common Adverse Drug Reactions: Thirst, dry mouth, asthenia, constipation, pollakiuria or polyuria, hyperglycemia.¹

Contraindications: Patients requiring urgent intervention to raise serum sodium acutely. Patients who are unable to sense or to respond appropriately to thirst. Patients with hypovolemic hyponatremia. Do not use with strong CYP 3A inhibitors. Patients who are anuric as no benefit is expected.¹

Manufacturer: Otsuka Pharmaceutical Co., Ltd.

Analysis: Samsca™ is the only oral selective vasopressin antagonist for the treatment of clinically significant hypervolemic and euvolemic hyponatremia. No dosage adjustment is necessary in patients with renal impairment and fluid restriction is not necessary for patients being treated with Samsca™. Samsca™ should be initiated and re-initiated in patients only in a hospital setting where serum sodium can be closely monitored due to the risk of overly rapid correction of hyponatremia. It has not been established that raising serum sodium with Samsca provides symptomatic benefit to patients. Due to the need for close monitoring of serum sodium, it is recommended that Samsca™ be added to the Preferred Drug List as a non-preferred drug.

IME Recommendation:

<input type="checkbox"/> Preferred Drug	<input type="checkbox"/> Recommended Drug
<input checked="" type="checkbox"/> Non-Preferred Drug	<input type="checkbox"/> Non-Recommended Drug
<input type="checkbox"/> Preferred Drug with Conditions	

1. Samsca™ [package insert]. Tokyo, Japan: Otsuka Pharmaceutical Co., Ltd.; 2009.