

SANCTURA XR[®] (trospium chloride extended release capsules) FACT SHEET

About SANCTURA XR[®] (trospium chloride extended release capsules)

- SANCTURA XR[®] is a once-daily medication approved by the U.S. Food and Drug Administration in August 2007 for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency.
- In clinical studies, SANCTURA XR[®] was shown to be effective and well tolerated, demonstrating significant improvements in OAB symptoms including frequency, urinary incontinence and urgency. Dry mouth is a common side effect in this drug class, and SANCTURA XR[®] has a low incidence of dry mouth – just 10.7 percent. This is significant because dry mouth has been shown to be one of the most common reasons for discontinuation of OAB therapy.¹ In two Phase 3 studies, constipation, dry mouth, and urinary retention led to discontinuation in 1 percent, 0.7 percent, and 0.5 percent of patients treated with SANCTURA XR[®] 60 mg daily, respectively.
- SANCTURA XR[®] belongs to a drug class of anticholinergic agents known as muscarinic receptor antagonists, which work by relaxing smooth muscle tissue found in the bladder, thus decreasing bladder contractions that are thought to be a cause of OAB.
- Based on in vitro data, no clinically relevant metabolic drug-drug interactions are anticipated. Some drugs which are actively secreted by the kidney may interact with SANCTURA XR[®] by competing for renal tubular secretion. For additional drug-drug interactions, please see Important Safety Information.

Important Safety Information

Contraindications: SANCTURA XR[®] is contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma, and in patients who are at risk for these conditions. It is also contraindicated in patients who have demonstrated hypersensitivity to the drug or any of its ingredients.

Warnings and Precautions: SANCTURA XR[®] should be administered with caution to patients with clinically significant bladder outflow obstruction or gastrointestinal obstructive disorders due to risk of urinary or gastric retention. SANCTURA XR[®], like other antimuscarinic agents, may decrease gastrointestinal motility and should be used with caution in patients with conditions such as ulcerative colitis, intestinal atony, and myasthenia gravis. In patients being treated for narrow-angle glaucoma, SANCTURA XR[®] should be used only if the potential benefits outweigh the risks, and in that circumstance only with careful monitoring. SANCTURA XR[®] is not recommended for use in patients with severe renal impairment (creatinine clearance <30 mL/minute). Alcohol should not be consumed within 2 hours of SANCTURA XR[®] administration. In addition, patients should be informed that alcohol may enhance the drowsiness caused by anticholinergic agents.

Drug Interactions: Trospium is metabolized by ester hydrolysis and excreted by the kidneys through a combination of tubular secretion and glomerular filtration. Based on in vitro data, no clinically relevant metabolic drug-drug interactions are anticipated with SANCTURA XR[®]. Some drugs which are actively secreted by the kidney may interact with SANCTURA XR[®] by competing for renal tubular secretion.

Concomitant use with other antimuscarinic agents that produce dry mouth and constipation and other anticholinergic effects may increase the frequency and/or severity of such effects. SANCTURA XR[®] may potentially alter the absorption of some concomitantly administered drugs due to anticholinergic effects

¹ Anderson RU, Davila GW, Cardarelli WJ, Forrester L. Improving outcomes in the management of overactive bladder and incontinence: new treatment options offer opportunities for fewer adverse effects and better compliance. *First Report*[®]. Millstone Township, NJ: Princeton Media Associates, LLC; January 2004:1-7

on GI motility. Concomitant use with digoxin did not affect the pharmacokinetics of either drug. Exposure to trospium on average was comparable in the presence of and without antacid. However, some individuals demonstrated increases or decreases in trospium exposure in presence of antacid. The clinical relevance of these findings is not known. The oral bioavailability was reduced following a high-fat content meal.

Adverse Reactions: The most common adverse reactions with SANCTURA XR[®] were dry mouth (10.7%) and constipation (8.5%).

About Overactive Bladder (OAB)

Overactive bladder is a medical condition whose symptoms include urinary frequency, urgency, and urge urinary incontinence, the accidental loss of urine that occurs after the strong, sudden urge to urinate. OAB is estimated to affect approximately 33 million Americans² and for many patients can cause medical and psychosocial problems. OAB is most prevalent among the elderly and strikes women twice as frequently as men.

For additional information on SANCTURA XR[®], please see [full prescribing information](#).

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² Sussman DO. Overactive bladder: treatment options in primary care medicine. *J Am Osteopath Assoc.* 2007;107:379-385