



Samsca[®] (tolvaptan) – Safety update

- On April 23, 2018, the [FDA approved](#) an update to the *Boxed Warning* and *Contraindications* sections of the [Samsca \(tolvaptan\)](#) drug label regarding use in patients with autosomal dominant polycystic kidney disease (ADPKD) outside of the FDA approved Risk Evaluation and Mitigation Strategy (REMS) and the risk of hepatotoxicity.
- Samsca is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia, including patients with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH).
 - Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with Samsca.
 - It has not been established that raising serum sodium with Samsca provides a symptomatic benefit to patients.
- Samsca can cause serious and potentially fatal liver injury and should not be prescribed or used outside of the FDA-approved REMS for ADPKD patients.
- Similar updates were made to the *Warnings and Precautions* section and the Medication Guide.



OptumRx[®] specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum[®] company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews[®] is published by the OptumRx Clinical Services Department.

©2018 Optum, Inc. All rights reserved.