



Oxtellar XR[®] (oxcarbazepine) – Expanded indication

- On December 14, 2018, [Supernus Pharmaceuticals announced](#) the FDA approval of [Oxtellar XR \(oxcarbazepine\)](#), for the treatment of partial-onset seizures in patients 6 years of age and older.
 - Previously, Oxtellar XR was approved as adjunctive therapy of partial seizures in adults and in children 6 years to 17 years of age.
- The use of Oxtellar XR for the treatment of partial onset seizures in pediatric patients 6 years of age and older is based on adequate and well-controlled studies of Oxtellar XR in adults, along with clinical trials of immediate-release oxcarbazepine in pediatric patients, and on pharmacokinetic evaluations of the use of Oxtellar XR in pediatric patients.
- In addition to the expanded indication, information regarding the risk of seizure aggravation was added to the *Warnings and Precautions* section of the Oxtellar XR drug label.
- The recommended initial adult dose for Oxtellar XR as monotherapy or adjunctive therapy is 600 mg/day given orally once daily for one week. Subsequent dosage increases can be made at weekly intervals in 600 mg/day increments to achieve the recommended daily dosage. The recommended daily dosage of Oxtellar XR is 1200 mg to 2400 mg/day, given once daily.
 - In pediatric patients 6 to less than 17 years of age, the recommended initial dosage is 8 mg/kg to 10 mg/kg orally once daily, not to exceed 600 mg per day in the first week. Subsequent dosage increases can be made at weekly intervals in 8 mg/kg to 10 mg/kg increments once daily, not to exceed 600 mg, to achieve the target daily dosage.



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.