IMPORTANT SAFETY INFORMATION

FOR PARTIAL-ONSET SEIZURES

WHAT COULD ONCE-DAILY DOSING MEAN FOR YOUR PATIENTS?

When your goal is to help patients be clear and in control, choose Oxtellar XR[®] with its extended-release formulation that provides a once-daily regimen.^{1,2}

Not actual patient.

INDICATION

Oxtellar XR[®] is indicated for the treatment of partial-onset seizures in patients 6 years of age and older.

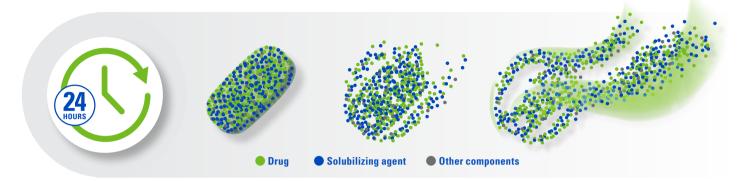
CONTRAINDICATIONS

Oxtellar XR is contraindicated in patients with a known hypersensitivity to oxcarbazepine, or to any of the components of Oxtellar XR, or to eslicarbazepine acetate. Reactions have included anaphylaxis and angioedema.



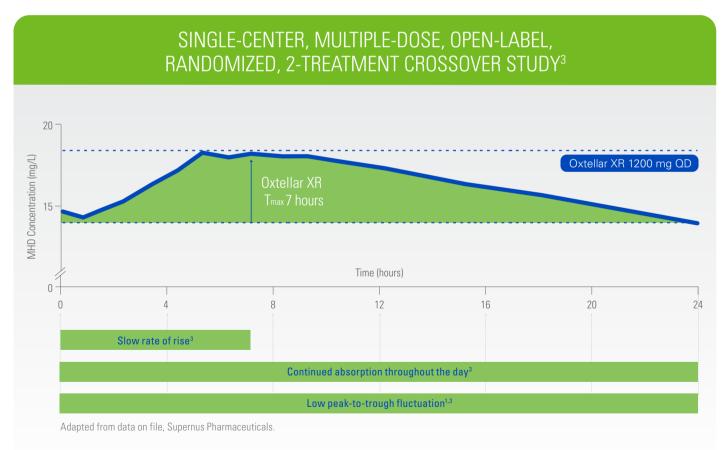
Patented delivery offers patients an even and controlled rate of absorption¹⁻³

Solutrol[®] extended-release technology uses a unique matrix including drug and solubilizing agent to release oxcarbazepine evenly and in a controlled manner to provide delivery over 24 hours.¹⁻³



For illustration purposes only; does not represent Oxtellar XR or the actual time medicine is released.

MHD plasma concentrations in healthy adults at steady state¹⁻³



Abbreviations: MHD, 10-monohydroxy derivative; QD, once daily; Tmax, time to peak drug concentration.

Please refer to the Important Safety Information (page 4) and the full <u>Prescribing Information</u> for complete information on Oxtellar XR, or visit <u>www.OxtellarXRhcp.com</u>.

Do you have patients who could benefit from once-daily dosing?

Perhaps you have patients in your practice who illustrate the following common situations:

- Difficulty maintaining a twice-daily dosing regimen
- Difficulty tolerating their current treatment
- Are experiencing breakthrough seizures
- Are going through changes to their lifestyle or keeping a busier schedule

Oxtellar XR offers:

- Simplified dosing regimen¹
- 1 week to 1200 mg/day once-daily maintenance dose in adults¹
- Steady bioavailability of treatment in the patient if taken compliantly³
- Low peak-to-trough fluctuation^{1,3}

Administering Oxtellar XR¹



- Patients should take Oxtellar XR on an EMPTY STOMACH at least 1 hour before or at least 2 hours after meals
- Oxtellar XR tablets should be swallowed whole. Do not cut, crush, or chew the tablets
- Lower-strength tablets (150 mg tablets) are available for pediatric patients or patients with difficulty swallowing
- For patients with severe renal impairment, are taking other AEDs, or are taking contraceptives, see full dosing considerations in full Prescribing Information

Abbreviation: AEDs, antiepileptic drugs.

Please refer to the Important Safety Information (page 4) and the full <u>Prescribing Information</u> for complete information on Oxtellar XR, or visit <u>www.OxtellarXRhcp.com</u>.

Oxtellar XR (oxcarbazepine) extended-release tablets for oral use

INDICATION

Oxtellar XR® is indicated for the treatment of partial-onset seizures in patients 6 years of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

• Oxtellar XR is contraindicated in patients with a known hypersensitivity to oxcarbazepine, or to any of the components of Oxtellar XR, or to eslicarbazepine acetate. Reactions have included anaphylaxis and angioedema.

WARNINGS & PRECAUTIONS

- Clinically significant hyponatremia (sodium <125 mmol/L) may develop during treatment. Measurement and laboratory tests of serum sodium concentrations should be considered for patients during maintenance treatment with Oxtellar XR, particularly if the patient is receiving other medications known to decrease serum sodium levels. Discontinuation of oxcarbazepine treatment may be clinically required.
- Rare cases of anaphylaxis and angioedema involving the larynx, glottis, lips, and eyelids have been reported in patients after taking the first or subsequent doses of oxcarbazepine. Angioedema associated with laryngeal edema can be fatal. If a patient develops any of these reactions after treatment with Oxtellar XR, the drug should be discontinued and an alternative treatment started. Do not rechallenge these patients with Oxtellar XR.
- Approximately 25% to 30% of patients who have had hypersensitivity reactions to carbamazepine will experience hypersensitivity reactions with Oxtellar XR. Patients with a history of hypersensitivity reactions to carbamazepine should ordinarily be treated with Oxtellar XR only if the potential benefit justifies the potential risk. Discontinue Oxtellar XR immediately if signs or symptoms of hypersensitivity develop.
- Serious dermatological reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with oxcarbazepine use. Should a patient develop a skin reaction while using Oxtellar XR, consideration should be given to discontinuing its use. (Please see WARNINGS section of complete prescribing information.)
- Anyone considering prescribing Oxtellar XR must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which antiepileptic drugs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during Oxtellar XR treatment, the prescriber needs to consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.
- Withdrawal of Oxtellar XR should be done gradually to minimize the potential of increased seizure frequency and status epilepticus.
- Multi-organ hypersensitivity reactions have occurred in patients on oxcarbazepine therapy. Some of these cases resulted in
 hospitalization and some were life-threatening. Signs and symptoms of this disorder were diverse; however, patients typically, although
 not exclusively, presented with fever and rash associated with other organ system involvement disorders. If an alternative etiology cannot
 be established, discontinue Oxtellar XR.
- Rare reports of hematologic events such as pancytopenia, agranulocytosis, and leukopenia have been seen in patients treated with oxcarbazepine and discontinuation of therapy should be considered if any evidence of these hematologic events develop.
- Due to physiological changes during pregnancy, plasma concentrations of the active metabolite of oxcarbazepine may gradually decrease throughout pregnancy. An increase in seizure frequency may occur. Monitor patients carefully during pregnancy and through the postpartum period.
- Exacerbation of or new onset primary generalized seizures has been reported with immediate-release oxcarbazepine. The risk is seen especially in children, but may also occur in adults. Discontinue Oxtellar XR if it occurs.
- Data on a limited number of pregnancies from pregnancy registries suggest that oral clefts and ventricular septal defects are associated with oxcarbazepine monotherapy use.

DOSING CONSIDERATIONS

- Enzyme inducing antiepileptic drugs such as carbamazepine, phenobarbital, and phenytoin decrease the exposure to MHD, the active metabolite of Oxtellar XR. Dosage increases or discontinuation of enzyme inducers may be necessary.
- In adult patients with severe renal impairment, initiate Oxtellar XR at a lower starting dose and increase, if necessary, at a slower than usual rate until the desired clinical response is achieved.
- Use of Oxtellar XR with certain hormonal contraceptives may decrease hormone plasma levels and render these contraceptives less effective. Additional or alternative non-hormonal forms of contraception are recommended.

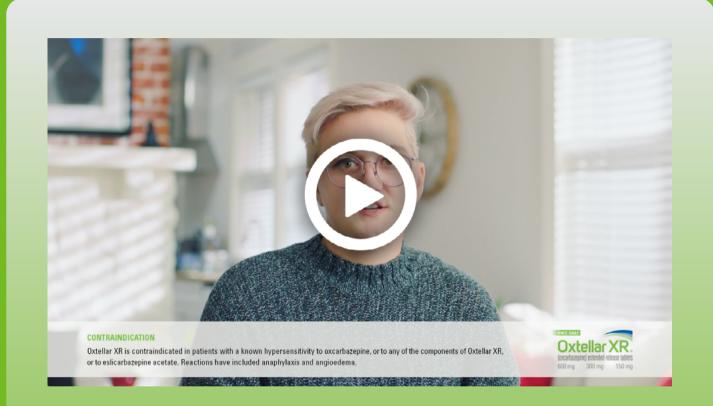
ADVERSE REACTIONS

The most commonly observed adverse reactions (\geq 5% and more frequent than placebo) seen in adults were (1200 mg, 2400 mg, v placebo): dizziness (20%, 41%, v 15%), somnolence (12%, 14%, v 9%), headache (8%, 15%, v 7%), balance disorder (5%, 7%, v 5%), tremor (5%, 1%, v 2%), vomiting (6%, 15%, v 9%), diplopia (10%, 13%, v 4%), asthenia (3%, 7%, v 1%), and fatigue (6%, 3%, v 1%). Adverse reactions in pediatric patients are similar to those seen in adults.

Please refer to the full <u>Prescribing Information</u> for complete information on Oxtellar XR.

See how 24-hour drug coverage helped make a difference for Grace

Visit the **<u>Real Patient Stories</u>** page on the website where you can watch videos that chronicle a patient's journey on Oxtellar XR. You can also hear from Dr. Wheless as he provides a peer perspective of why he chose once-daily Oxtellar XR for his patient, Grace.





Watch their story at <u>www.OxtellarXRhcp.com/real-patient-stories</u> or use your mobile device to scan the QR code.

Please refer to the Important Safety Information (page 4) and the full <u>Prescribing Information</u> for complete information on Oxtellar XR, or visit <u>www.OxtellarXRhcp.com</u>.

Choose a therapy that's right for your patient

"If a medication has an extended-release option I am always an advocate of it, because we want the patient to have an even amount of that medication throughout the day. And the second component is having the ease of a patient being able to take a once-daily dose. We want to be able to amplify their ability to stick to their dosing."*



Monali Patel, MD Division of Neurology SENTA Medical Center, San Diego, CA

*Oxtellar XR has not been shown to improve adherence.

Consider prescribing once-daily Oxtellar XR for your patients

Order samples online with no patient info needed



Get started at <u>www.OxtellarXRhcp.com</u> or use your mobile device to scan the QR code.



References:

1. Oxtellar XR. Package insert. Supernus Pharmaceuticals Inc. 2. French JA, Baroldi P, Brittain ST, Johnson JK; PROSPER Investigators Study Group. Efficacy and safety of extended-release oxcarbazepine (Oxtellar XR™) as adjunctive therapy in patients with refractory partial-onset seizures: a randomized controlled trial. *Acta Neurol Scand.* 2014;129(3):143-153. doi:10.1111/ane.12207 3. Data on file. Supernus Pharmaceuticals Inc.

Please refer to the Important Safety Information (page 4) and the full <u>Prescribing Information</u> for complete information on Oxtellar XR, or visit <u>www.OxtellarXRhcp.com</u>.

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