

FOR PARTIAL-ONSET SEIZURES

# JOEL'S GOAL IS TO BE CLEAR AND IN CONTROL.



## Meet Joel

**Age:** 44

**Occupation:** Construction Manager

**Diagnosis:** Epilepsy with partial-onset seizures

**Current Treatment:** Oxcarbazepine IR 600mg BID

### Challenges:

- Has had reliable partial-onset seizure control while on OXC IR but sometimes forgets to take his medication throughout the day\*
- Joel works a stressful job with long hours and is hoping to simplify his routine with once-daily dosing

**Abbreviations:** BID, two-times a day; IR, immediate release; OXC, oxcarbazepine

\*Oxtellar XR has not been shown to improve adherence.

**Does Joel sound similar to patients in your practice?**

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.



Please refer to the Important Safety Information (page 2) and the full Prescribing Information for complete information on Oxtellar XR, or visit [www.OxtellarXRhcp.com](http://www.OxtellarXRhcp.com).

## 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.

Consider making Oxtellar XR® (oxcarbazepine) your sodium channel blocker of choice for patients like Joel.



Joel, age 44; construction manager

Patient

Presentation

Recurrent partial-onset seizures after a car accident

Diagnosis

Frontal lobe epilepsy with partial-onset seizures

Treatment

Initiated on Oxcarbazepine IR at diagnosis. Currently taking 600mg BID

Appointment Notes

Joel has seen seizure improvement on his current treatment, but is looking for a once-daily option to simplify his routine

Treatment Decision

Joel's physician decides to transition him to Oxtellar XR



## Patented delivery offers Joel an even and controlled rate of absorption<sup>1-3</sup>

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.<sup>1-3</sup>

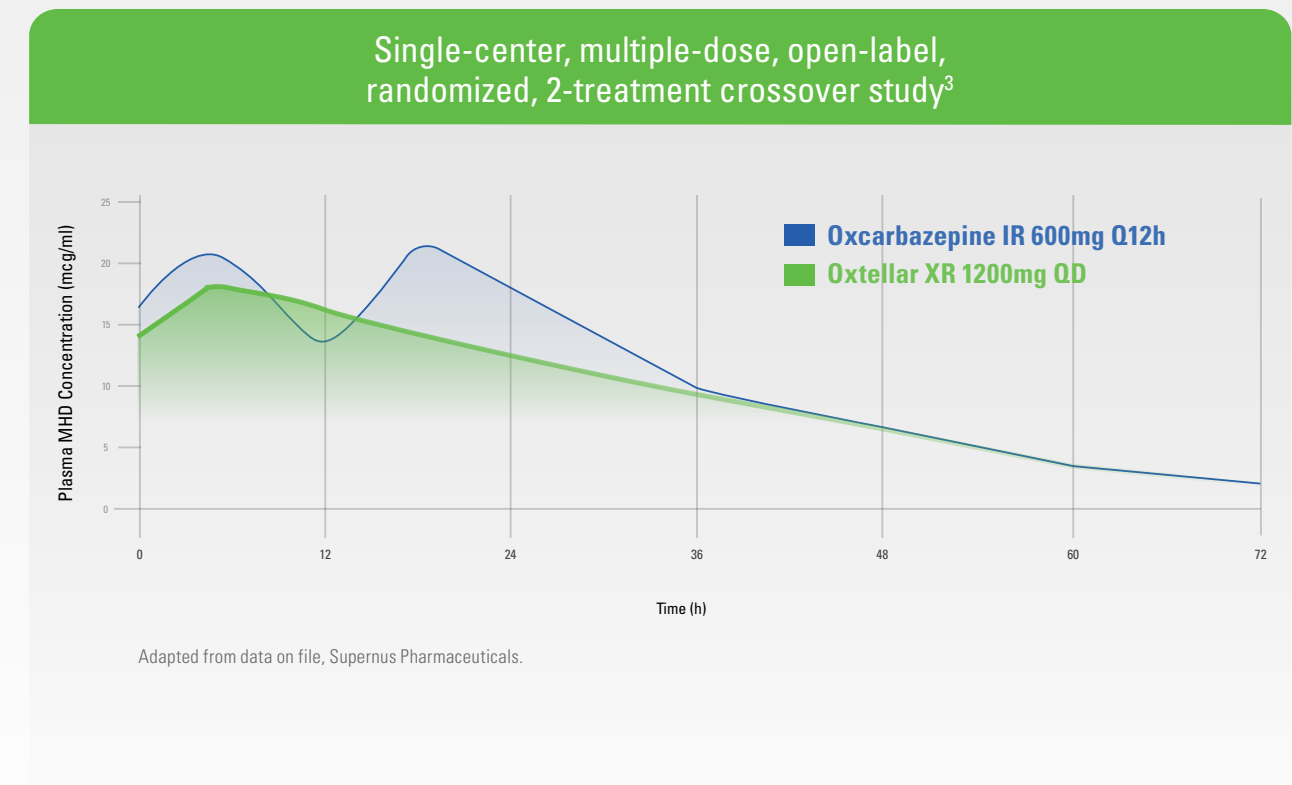


For illustration purposes only; does not represent Oxtellar XR or the actual time medicine is released.

Visit [www.OxtellarXRhcp.com](http://www.OxtellarXRhcp.com) to learn more about the pharmacokinetic profile of Oxtellar XR.

## Steady 24-hour absorption with low fluctuation<sup>1,3</sup>

MHD plasma concentrations in healthy adults at steady state<sup>1-3</sup>



Abbreviations: AEDs, antiepileptic drugs; MHD, 10-monohydroxy derivative; QD, once-daily.

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## Oxtellar XR has a once-daily dosing regimen with a convenient titration schedule

**1 WEEK to 1200 mg/day**  
once-daily maintenance dose in adults<sup>1</sup>



- Initiate treatment at a dosage of 600 mg/day given orally once daily for 1 week. Subsequent dosage increases can be made at weekly intervals in 600 mg/day increments<sup>2</sup>
- Maintain at 1200 mg/day to 2400 mg/day once daily<sup>2</sup>

### IMPORTANT SAFETY INFORMATION (CONT'D)

#### 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.

## Help patients like Joel start and stay on Oxtellar XR<sup>1</sup>

QD dosing with  
**3** dosage strengths<sup>1</sup>

Tablets shown are not actual size.



600 mg

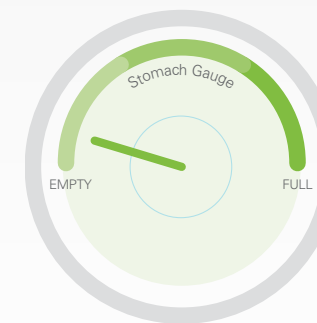


300 mg



150 mg

## Administering Oxtellar XR<sup>1</sup>



- **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
- See dosing considerations on page 2 for patients with severe renal impairment, taking other AEDs, or taking contraceptives

**Abbreviation:** AEDs, antiepileptic drugs.

Please refer to the Important Safety Information (page 2) and the full [Prescribing Information](#) for complete information on Oxtellar XR, or visit [www.OxtellarXRhcp.com](http://www.OxtellarXRhcp.com).



FOR PARTIAL-ONSET SEIZURES

# HELP JOEL WITH HIS GOAL TO BE CLEAR AND IN CONTROL.

Consider Oxtellar XR for  
your patients like Joel.

Visit [www.OxtellarXR.com/Joel](http://www.OxtellarXR.com/Joel)  
to order samples and for  
additional information.



Proven partial-onset seizure  
medication that provides  
controlled delivery over  
24 hours<sup>1-3</sup>



Once-daily dosing with a  
convenient titration schedule<sup>1</sup>



Co-pay savings program so eligible,  
commercially approved patients pay  
as little as \$0 for their next  
2 prescriptions<sup>†</sup>

Not actual patients.

<sup>†</sup>For full terms and conditions, please see the Oxtellar XR co-pay savings card, or visit [www.OxtellarXR.com](http://www.OxtellarXR.com).

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### References:

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

