FOR PARTIAL-ONSET SEIZURES

TRICIA'S GOAL IS TO BE CLEAR AND IN CONTROL.

Not actual patient.

Meet Tricia

Age: 42

Occupation: Local news anchor

Diagnosis: Epilepsy with partial-onset seizures

Current Treatment: Levetiracetam 1500mg BID

Challenges:

- Had previously experienced seizure control for several years with levetiracetam
- Recent increase in breakthrough partial-onset seizures
- Is willing to discuss adding adjunctive treatment, but would prefer it be a once-a-day medication

Does Tricia sound similar to patients in your practice?

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.

ONCE-DAILY

Oxtellar XR®

(oxcarbazepine) extended-release tablets

600 mg 300 mg 150 mg

Abbreviation: BID, twice a day.

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.

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 (≥ 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.

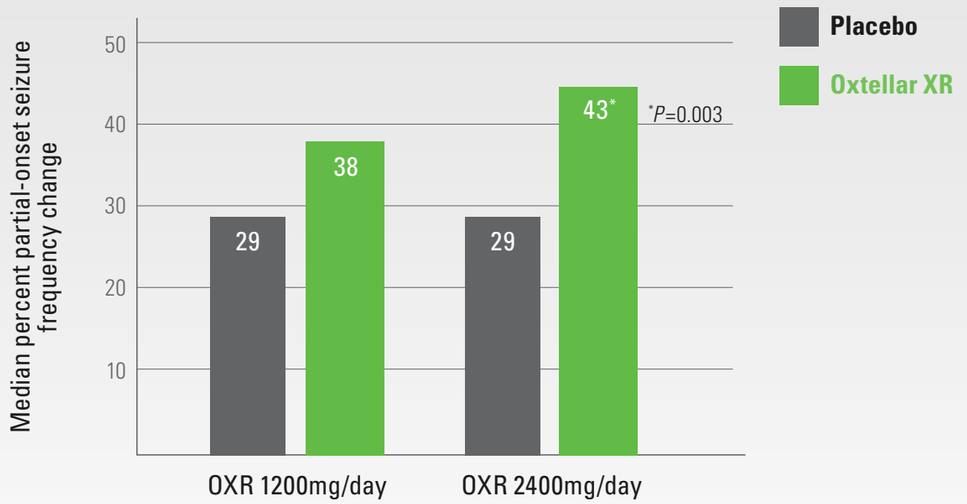
Please refer to the full Prescribing Information for complete information on Oxtellar XR, or visit www.OxtellarXRhcp.com.

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

Patient	Presentation	Diagnosis	Treatment	Appointment Notes	Treatment Decision
Tricia, aged 42; local news anchor	Recurrent partial-onset seizures following a head injury	Temporal lobe epilepsy with partial-onset seizures	Levetiracetam started at initial presentation of partial-onset seizures; currently taking 3000 mg (1500 mg BID) • Had seizure improvement initially • 3 years later, breakthrough partial-onset seizures started to occur	Tricia would like to control her partial-onset seizures with a convenient treatment that works for her	Tricia's physician decides to add Oxtellar XR to her current treatment regimen

Demonstrated efficacy as adjunctive therapy in patients like Tricia with partial-onset seizures[1-4]

PHASE 3 TRIAL[1-3]



A multinational, multicenter, double-blind, randomized, placebo-controlled, 3-arm, parallel-group Phase 3 trial evaluating the safety and efficacy of OXR 1200mg/day (n=122) or OXR 2400mg/day (n=123) vs. placebo (n=121) in adult patients (aged 18 to 66) having a diagnosis of epilepsy with uncontrolled partial-onset seizures with or without secondary generalization (baseline frequency ≥3 seizures/28 days). Participants were taking a stable regimen of 1 to 3 concomitant AED(s) and experiencing an average of 6 partial-onset seizures per 28 days.

OLE STUDY DESIGN[4]

Blinded conversion over 3 weeks to 12-month, open-label, once-daily Oxtellar XR 1200 mg/day

Subsequent dose adjustments as clinically indicated (increments/decrements, 300 mg/day to 600 mg/day; maximum dosage, 2400 mg/day)

OLE Study Limitations[4]

AED additions/withdrawals may influence partial-onset seizure control. Many patients entering OLEs have already demonstrated tolerability of study medication during double-blind treatment and, therefore, may be less likely to withdraw due to AEs. Patient retention may also be influenced by the intensive follow-up that occurs in a clinical study

Abbreviations: AEs, adverse events; AEDs, antiepileptic drugs; OLE, open-label extension; OXR, Oxtellar XR

IMPORTANT SAFETY INFORMATION (CON'T)

CONTRAINDICATIONS

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Tricia wants a proven therapy with demonstrated tolerability

AEs occurring in ≥5% of patients receiving Oxtellar XR with concomitant AEDs and more frequent than with placebo[1-4]

	PHASE 3 TRIAL			OLE
	Oxtellar XR 2400 mg/day (n=123)	**Oxtellar XR 1200 mg/day** (n=122)	Placebo (n=121)	**Oxtellar XR 600 to 2400 mg/day** (n=214)
Dizziness	41%	**20%**	15%	**15%**
Somnolence	14%	**12%**	9%	**6%**
Nausea	12%	**12%**	12%	**8%**
Diplopia	13%	**10%**	4%	**9%**
Headache	15%	**8%**	7%	**11%**
Fatigue	3%	**6%**	1%	**0%**
Vomiting	15%	**6%**	9%	**6%**
Tremor	1%	**5%**	2%	**0%**
Balance disorder	7%	**5%**	5%	**5%**
Asthenia	7%	**3%**	1%	**0%**
Upper respiratory tract infection	0%	**0%**	0%	**5%**

For a complete listing of AEs greater than or equal to 2%, see full Prescribing Information.

A majority of patients in clinical trials remained on treatment with Oxtellar XR[1-4]

Clinical trial patients were on 1 to 3 concomitant AEDs, which included carbamazepine, valproate, lamotrigine, levetiracetam, topiramate, and phenytoin[3]

PHASE 3 1200 MG/DAY GROUP[2]

Only 15% of patients

discontinued treatment due to AEs in the Phase 3 trial

OLE (Oxtellar XR 600-2400 mg/day)[3,4]

Only 5% of patients

discontinued treatment due to AEs in the one-year OLE

Discontinuation rate due to AEs in the Phase 3 Oxtellar XR study was 30% in the 2400 mg/day group, 15% in the 1200 mg/day group, and 8% in the placebo group.[3]

Many patients entering OLEs have already demonstrated tolerability of study medication during double-blind treatment and, therefore, may be less likely to withdraw due to AEs.

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

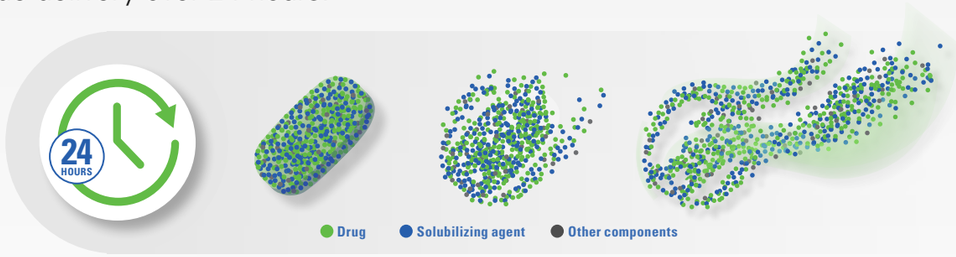
1 WEEK to 1200 mg/day

once-daily maintenance dose in adults[1]

- 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[1]
- Maintain at 1200 mg/day to 2400 mg/day once daily[1]

Patented delivery offers Tricia an even and controlled rate of absorption[1-3]

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.



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

Visit www.OxtellarXRHCP.com to watch a video about Solutrol® extended-release technology.

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 XRTM) 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. **4.** Chung SS, Johnson JK, Brittain ST, Baroldi P. Long-term efficacy and safety of adjunctive extended-release oxcarbazepine (Oxtellar XR®) in adults with partial-onset seizures. *Acta Neurol Scand.* 2016;133(2):124-130.

FOR PARTIAL-ONSET SEIZURES

HELP TRICIA WITH HER GOAL TO BE CLEAR AND IN CONTROL.

Consider Oxtellar XR for your patients like Tricia.

Visit OxtellarXR.com/Tricia to order samples and for additional information.

- Demonstrated safety profile and efficacy as adjunctive therapy in patients with partial-onset seizures[1-4]
- Once-daily dosing with a convenient titration schedule[1]
- Only 5% of patients discontinued due to AEs in a 12-month add-on OLE study[3,4] (Please see the OLE study limitations on page 3)
- Co-pay savings program so eligible, commercially approved patients pay as little as $0 for their next 2 prescriptions*

Not actual patient.

*For full terms and conditions, please see the Oxtellar XR co-pay savings card, or visit www.OxtellarXR.com.

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(oxcarbazepine) extended-release tablets
600 mg 300 mg 150 mg

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