

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

Meet Grace

Age: 26

Occupation: Frontline paramedic

Diagnosis: Temporal lobe epilepsy with partial-onset seizures

Current Treatment: Eslicarbazepine acetate 1800 mg/day QD

Challenges:

- Diagnosed with partial-onset seizures at 14
- Has experienced breakthrough partial-onset seizures on several AEDs prior to being prescribed eslicarbazepine acetate
- Is still having breakthrough partial-onset seizures on current medication
- Has a busy school and work schedule and prefers the simplicity of a once-daily medication

Does Grace sound similar to patients in your practice?



Grace, Oxtellar XR patient

Abbreviations: QD, every day dosing; AEDs, antiepileptic drugs.

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

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

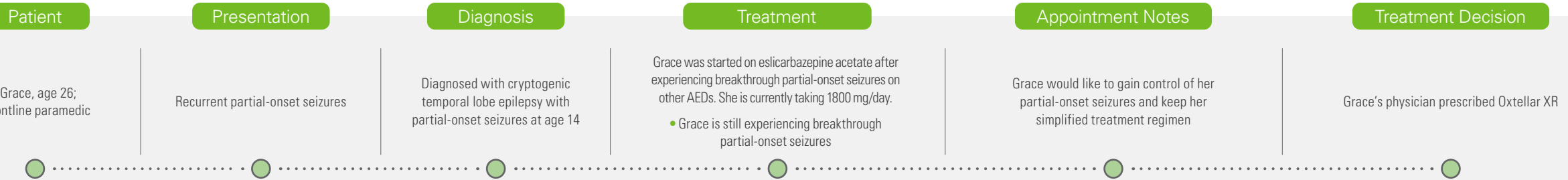
The most commonly observed adverse reactions (≥ 5% and more frequent than placebo) seen in adults were (1200 mg, 2400 mg, v placebo): dizziness (20%, 41%, v 15%), somnolence (12%, 14%, v 9%), headache (8%, 15%, v 7%), balance disorder (5%, 7%, v 5%), tremor (5%, 1%, v 2%), vomiting (6%, 15%, v 9%), diplopia (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.

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



Grace, age 26; frontline paramedic



A proven monotherapy for patients like Grace who have refractory partial-onset seizures

In an 18-week, multicenter, randomized, double-blind, dose-controlled, monotherapy substitution study, patients with medically refractory partial-onset epilepsy received monotherapy with OXC 2400 mg/day vs. OXC 300 mg/day.*¹

Primary Endpoint: The percentage of patients meeting 1 of the exit criteria was significantly lower ($P < 0.0001$) for the OXC 2400 mg/day treatment group 14/34 (41%) relative to the OXC 300 mg/day treatment group 42/45 (93%).¹

Grace wants both efficacy and safety

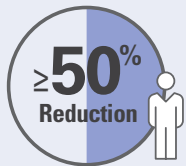
Phase 3 study: efficacy and safety (including long-term safety) of Oxtellar XR as adjunctive therapy in patients with refractory partial-onset seizures²⁻⁵

Efficacy and safety of Oxtellar XR was evaluated in a multinational, multicenter, double-blind, randomized, placebo-controlled, 3-arm, parallel-group, phase 3 trial of 366 adult patients having a diagnosis of epilepsy with uncontrolled partial-onset seizures with or without secondary generalization, taking a stable regimen of 1 to 3 concomitant AED(s), experiencing an average of 6 partial-onset seizures per 28 days.²⁻⁴

Demonstrated tolerability is important to Grace

AEs occurring in ≥5% of patients receiving Oxtellar XR with concomitant AEDs and more frequent than with placebo²⁻⁵

Responder Rate*



42%

of patients in the 2400 mg/day group had a ≥50% reduction in seizure frequency when converted to OXC monotherapy from 1 to 2 AED(s)¹



12%

of patients in the 2400 mg/day group were seizure free¹

In the 300 mg/day group, 7% of patients had a ≥50% reduction in seizure frequency and 0% of patients were seizure free.¹

The recommended dose of Oxtellar XR is between 1200 mg/day and 2400 mg/day.²

Oxtellar XR is the only AED that provides 24-hour, controlled delivery of OXC.^{2,3}

PHASE 3 TRIAL^{2,4}

Efficacy^{2,4}

Median percent partial-onset seizure frequency change over the 16-week, double-blind treatment period:

ITT population (N=366): 29% for placebo (n=121) vs. 38% ($P=0.078$) for Oxtellar XR 1200 mg/day (n=122) and 43% ($P=0.003$) for Oxtellar XR 2400 mg/day (n=123)

North American post hoc analysis (n=116): 13% for placebo (n=41) vs. 35% ($P=0.022$) for Oxtellar XR 1200 mg/day (n=40) and 53% ($P=0.006$) for Oxtellar XR 2400 mg/day (n=35)

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

OLE STUDY DESIGN⁵

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 Limitations⁵

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

PHASE 3 TRIAL

OLE

	Oxtellar XR 2400 mg/day (n=123)	Oxtellar XR 1200 mg/day (n=122)	Placebo (n=121)	Oxtellar XR 600-2400 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%

Only 15% discontinuation due to AEs in the Phase 3 Trial (1200 mg/day group)³

Only 5% discontinuation due to AEs in the OLE trial^{3,5}

For a complete listing of AEs ≥2%, see full Prescribing Information.

Oxtellar XR offers once-daily, controlled delivery of OXC with a convenient titration schedule²

1 WEEK to 1200 mg/day
once-daily maintenance dose in adults*²



*Higher doses may be necessary for some adult patients.

Abbreviations: AEs, adverse events; AEDs, antiepileptic drugs; ITT, intent to treat; OLE, open-label extension; OXC, oxcarbazepine.

References:

1. Beydoun A, Sachdeo RC, Rosenfeld WE, et al. Oxcarbazepine monotherapy for partial-onset seizures: a multicenter, double-blind, clinical trial. *Neurology*. 2000;54(12):2245-2251. doi:10.1212/wnl.54.12.2245 2. Oxtellar XR. Package insert. Supernus Pharmaceuticals Inc. 3. Data on file. Supernus Pharmaceuticals Inc. 4. 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 5. 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. doi:10.1111/ane.12467

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*87 patients aged 11 to 66 years with medically refractory partial-onset epilepsy participated in an 18-week, multicenter, randomized, double-blind, dose-controlled, monotherapy substitution study evaluating the safety and efficacy of monotherapy with OXC 2400 mg/day vs. OXC 300 mg/day (41 ITT patients received OXC 2400 mg/day and 46 ITT patients received OXC 300 mg/day).¹

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

"I just take Oxtellar XR once a day and I'm going to keep taking Oxtellar XR because it's doing its job."

- **Grace**
Oxtellar XR patient



Proven partial-onset seizure medication that provides controlled delivery over 24 hours²⁻⁴



In an 18-week clinical study of patients with refractory partial-onset epilepsy, 12% of patients were seizure free when converted to 2400 mg/day OXC monotherapy from 1 to 2 AED(s)¹



Only 5% of patients discontinued due to AEs in a 12-month add-on OLE study^{3,5} (Please see the OLE study limitations inside)

Consider Oxtellar XR for your patients like Grace.



Scan the QR code or see www.OxtellarXRhcp.com for samples and additional information

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