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

Meet Val*

Age: 37

Occupation: Data analyst

Diagnosis: Epilepsy with partial-onset seizures

Current Treatment: Eslicarbazepine acetate 1000 mg QD

Challenges:

- Initially started on levetiracetam but continued to experience periodic breakthrough partial-onset seizures; transitioned to eslicarbazepine acetate after 2 years
- Has noticed she has become forgetful and has difficulty staying awake throughout the work day†
- She has enjoyed the simplicity of a once-daily regimen

Does Val sound similar to patients in your practice?

*Not actual patient. Used for illustrative purposes.

†Oxtellar XR has not been shown to reduce memory impairment or somnolence.

Abbreviation: QD, every day.

ONCE-DAILY

Oxtellar XR®

(oxcarbazepine) extended-release tablets

600 mg 300 mg 150 mg

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.

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 Val.

Patient	Presentation	Diagnosis	Treatment	Appointment Notes	Treatment Decision
Val, age 37; data analyst	Recurrent partial-onset seizures after a sports injury	Frontal lobe epilepsy with partial-onset seizures	Initiated on levetiracetam at diagnosis. Currently taking eslicarbazepine acetate 1000 mg QD • Had seizure improvement initially but continues to have infrequent partial-onset seizures • Forgetfulness and difficulty staying awake are interfering with her ability to work	Val would like to control her partial-onset seizures with a treatment that works for her	Val's physician decides to transition her to Oxtellar XR

Help keep Val's regimen simple with once-daily Oxtellar XR

Oxtellar XR is the only AED that provides 24-hour controlled delivery of OXC, the sodium channel blocker with powerful evidence for the treatment of partial-onset seizures*,[1-14]

MONOTHERAPY TRIALS–OXC NUMBER OF TRIALS	
Comparative/new-onset partial-onset seizures[8-11]	4
Low-dose vs. high-dose therapy (refractory partial-onset seizures)[1,12]	2
Placebo-controlled trial (recent partial-onset seizures)[13]	1
Placebo-controlled trial (presurgical)[14]	1
Adjunctive Therapy Trials–OXC/Oxtellar XR†	
Placebo-controlled trials (refractory partial-onset seizures)[3,6,7]	3
Positive clinical trials	**11**

*The antiseizure effect of Oxtellar XR is primarily exerted through the 10-monohydroxy derivative (MHD) metabolite of OXC. The precise mechanism by which oxcarbazepine and MHD exert antiseizure activity is unknown but is thought to involve inhibition of voltage-sensitive sodium channels.

†In a multinational, multicenter, double-blind, randomized, placebo-controlled, 3-arm, parallel-group, phase 3 trial of 366 adult patients with epilepsy and uncontrolled partial-onset seizures with or without secondary generalization, taking a stable regimen of 1 to 3 concomitant AEDs experiencing an average of 6 partial-onset seizures per 28 days.[2-4]

Abbreviations: AEs, adverse events; AEDs, antiepileptic drugs; OLE, open-label extension; OXC, oxcarbazepine; QD, every day.

Val 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[2-4,15]

	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%**

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

ONLY 15% OF — **discontinued treatment due to AEs in the phase 3 trial (1200 mg/day group)[4]**

ONLY 5% OF — **discontinued treatment due to AEs in the 1-year OLE trial[4,15]**

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.[4]

OLE Study Limitations
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.[15]

Val needs a treatment chosen with cognitive AEs in mind

In the phase 3 trial for Oxtellar XR, cognitive AEs were:

- **Similar to placebo[4]**
- **<1% for both 1200 and 2400 mg/day doses[4]**

Oxtellar XR has a once-daily dosing regimen with a convenient titration schedule[2]

1 WEEK to 1200 mg/day

once-daily maintenance dose in adults*[,2]

Once-daily dosing offers patients controlled 24-hour partial-onset seizure medication coverage.[2,4]

*Higher doses may be necessary for some adult patients.

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.** 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 **4.** Data on file. Supernus Pharmaceuticals Inc. **5.** Glauser TA. Oxcarbazepine in the treatment of epilepsy. *Pharmacotherapy.* 2001;21(8):904-919. doi:10.1592/phco.21.11.904.34513 **6.** Barcs G, Walker EB, Elger CE, et al. Oxcarbazepine placebo-controlled, dose-ranging trial in refractory partial epilepsy. *Epilepsia.* 2000;41(12):1597-1607. doi:10.1111/j.1499-1654.2000.001597.x **7.** Glauser TA, Nigro M, Sachdeo RC, et al. Adjunctive therapy with oxcarbazepine in children with partial seizures. *Neurology.* 2000;54(12):2237-2244. doi:10.1212/wnl.54.12.2237 **8.** Christe W, Krämer G, Vigonius U, et al. A double-blind controlled clinical trial: oxcarbazepine versus sodium valproate in adults with newly diagnosed epilepsy. *Epilepsy Res.* 1997;26(3):451-460. doi:10.1016/s0920-1211(96)01013-3 **9.** Bill PA, Vigonius U, Pohlmann H, et al. A double-blind controlled clinical trial of oxcarbazepine versus phenytoin in adults with previously untreated epilepsy. *Epilepsy Res.* 1997;27(3):195-204. doi:10.1016/s0920-1211(97)00024-7 **10.** Guerreiro MM, Vigonius U, Pohlmann H, et al. A double-blind controlled clinical trial of oxcarbazepine versus phenytoin in children and adolescents with epilepsy. *Epilepsy Res.* 1997;27(3):205-213. doi:10.1016/s0920-1211(97)00025-9 **11.** Dam M. Oxcarbazepine in monotherapy. *Behav Neurol.* 1990;3(1):31-34. doi:10.3233/BEN-1990-31S105 **12.** Sachdeo RC, Beydoun A, Schachter S, et al. Oxcarbazepine (Trileptal) as monotherapy in patients with partial seizures. *Neurology.* 2001;57(5):864-871. doi:10.1212/wnl.57.5.864 **13.** Sachdeo RC, Edwards K, Hasegawa H, Rosenfeld W, Abou-khalil B, Zhou L, D'Souza J. Safety and efficacy of oxcarbazepine 1200 mg/day in patients with recent-onset partial epilepsy. Abstract presented at: 51st Annual AAN Meeting; April 21, 1999. Los Angeles, CA. **14.** Schachter SC, Vazquez B, Fisher RS, et al. Oxcarbazepine: double-blind, randomized, placebo control, monotherapy trial for partial seizures. *Neurology.* 1999;52(4):732-737. doi:10.1212/wnl.52.4.732 **15.** 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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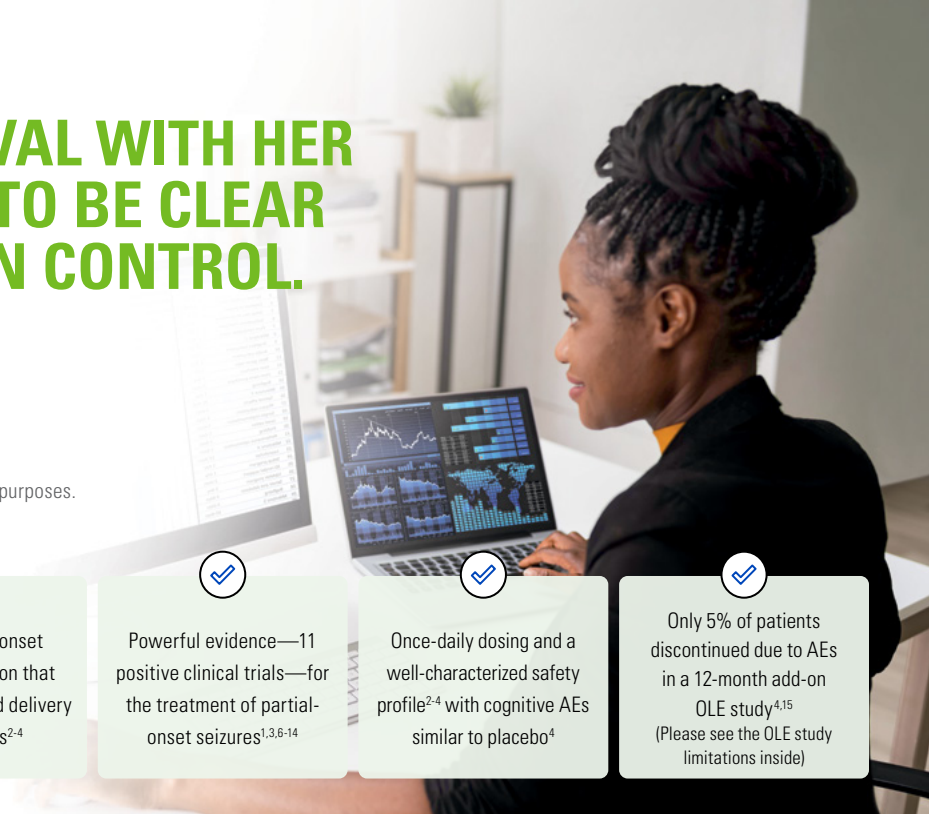
HELP VAL WITH HER GOAL TO BE CLEAR AND IN CONTROL.



Not actual patient.
Used for illustrative purposes.

- Proven partial-onset seizure medication that provides controlled delivery over 24 hours[2-4]
- Powerful evidence—11 positive clinical trials—for the treatment of partial-onset seizures[1,3,6-14]
- Once-daily dosing and a well-characterized safety profile[2-4] with cognitive AEs similar to placebo[4]
- Only 5% of patients discontinued due to AEs in a 12-month add-on OLE study[4,15] (Please see the OLE study limitations inside)

Consider Oxtellar XR for your patients like Val.

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

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