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

**Give him proven partial-onset seizure medication that has controlled delivery over 24 hours.[1-4]**

Not actual patient. Used for illustrative purposes.

**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 full Prescribing Information and Important Safety Information (pages 2 and 3) for complete information on Oxtellar XR, or visit www.OxtellarXR.com.**

ONCE-DAILY

Oxtellar XR®

(oxcarbazepine) extended-release tablets

600 mg 300 mg 150 mg



**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 full 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.



## WARNINGS & PRECAUTIONS (continued)

- 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.

# He wants effective partial-onset seizure control.

ONCE-DAILY
Oxtellar XR®
(oxcarbazepine) extended-release tablets
600 mg 300 mg 150 mg

## 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 # of trials

| | |
|---|---|
| Comparative/new-onset partial-onset seizures[5-8] | 4 |
| Low-dose vs. high-dose therapy (refractory partial-onset seizures)[2,9] | 2 |
| Placebo-controlled trial (recent partial-onset seizures)[10] | 1 |
| Placebo-controlled trial (presurgical)[11] | 1 |

### Adjunctive therapy trials—OXC/Oxtellar XR

| | |
|---|---|
| Placebo-controlled trials (refractory partial-onset seizures)[4,12,13] | 3 |

## Positive clinical trials:

**11**

Abbreviations: AED, antiepileptic drug; OXC, oxcarbazepine.



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# He wants effective partial-onset seizure control.

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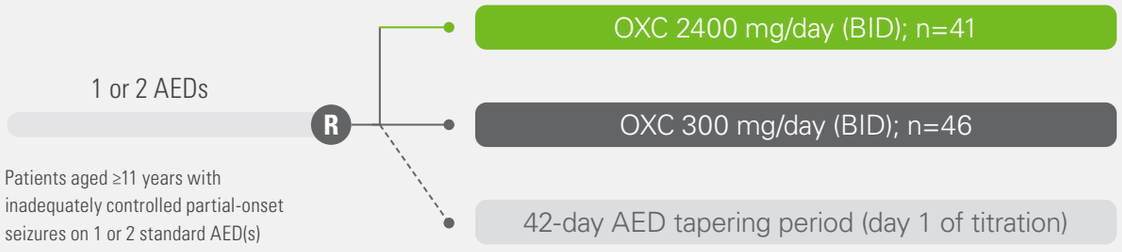
## A monotherapy with the power to improve partial-onset seizure control[2]

### Study Design

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 in 87 patients aged 11 to 66 years with medically refractory partial-onset epilepsy (41 ITT patients receiving OXC 2400 mg/day and 46 ITT patients receiving OXC 300 mg/day). The study included a 56-day baseline phase, followed by an 18-week double-blind treatment phase, which comprised a 14-day titration period and a 112-day maintenance period. Median numbers of partial-onset seizures per 28 days at baseline were 10.5 for the OXC 2400 mg/day group and 6.5 for the OXC 300 mg/day group.[2]




Abbreviations: AEs, adverse events; AED, antiepileptic drug; ITT, intent to treat; OXC, oxcarbazepine.

### Study Results—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%).[2]

## Improved partial-onset seizure control in patients previously taking 1 to 2 AED(s)[2]

### Study Results—Responder Rate

Percentage of patients transitioned to OXC monotherapy who were previously taking 1 to 2 AED(s) and achieved ≥50% reduction in partial-onset seizures.[2]



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# He needs both efficacy *and* proven safety.

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600 mg 300 mg 150 mg

## Demonstrated safety and efficacy as adjunctive therapy in patients with partial-onset seizures[1,4,14-16]

### Phase 3 Trial [1,4,14]

A multinational, multicenter, double-blind, randomized, placebo-controlled, 3-arm, parallel-group phase 3 trial

#### Patient Population [1,4,14]

N=366

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)

Taking a stable regimen of 1 to 3 concomitant AED(s)

Experiencing an average of 6 partial-onset seizures per 28 days

#### Efficacy [1,4,15]

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)

### OLE Study Design[14,16]

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[16]

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: AED, antiepileptic drug; AEs, adverse events; ITT, intent to treat; OLE, open-label extension.



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## AEs occurring in ≥5% of patients receiving Oxtellar XR with concomitant AEDs and more frequent than with placebo[1,4,14,16]

| | 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.

**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.[14]**

Abbreviations: AEs, adverse events; AED, antiepileptic drug; OLE, open-label extension.



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# He is clear on what he needs from his treatment.

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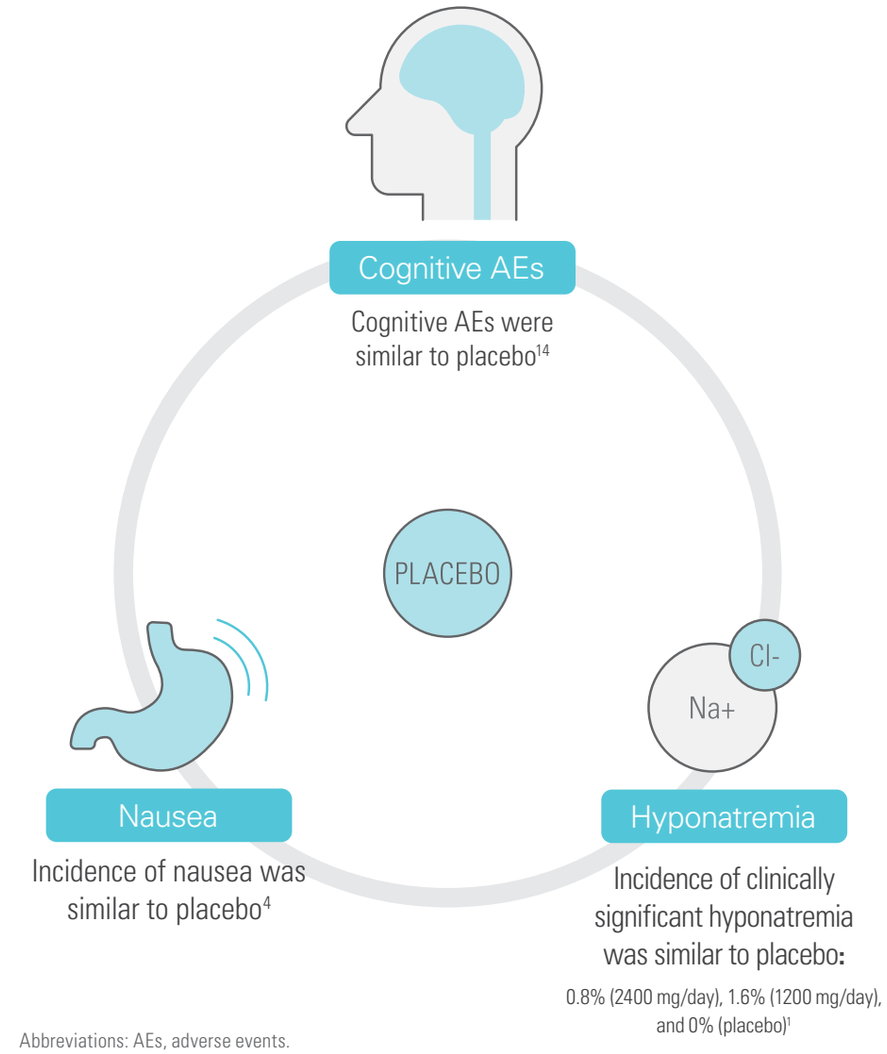
(oxcarbazepine) extended-release tablets
600 mg 300 mg 150 mg

## Choose a therapy that's right for your patient[1,4,14]

"Tolerability is an extremely important topic in choosing antiepileptics for my patients. **One thing I consider is cognitive function and cognitive impairment, and I'm comfortably able to say to my patients that cognitive impairment is not something that I typically see with Oxtellar XR, but we will monitor for it.** Because no patients, especially those with epilepsy, want to feel that they won't be able to think clearly."[14]

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

### Phase 3 Study Results




Abbreviations: AEs, adverse events.

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# A majority of patients in clinical trials remained on treatment with Oxtellar XR[4,14,16]

Clinical trial patients were on 1 to 3 concomitant AEDs, which included carbamazepine, valproate, lamotrigine, levetiracetam, topiramate, and phenytoin[14]

**Only 15%**
of patients discontinued treatment due to AEs in the phase 3 trial

Phase 3 1200 mg/day group[14]

**Only 5%**
discontinuation rate due to AEs in the one-year OLE

OLE (Oxtellar XR 600-2400 mg/day)[14,16]

**OLE Study Limitations:** 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; AED, antiepileptic drug; OLE, open-label extension.

## He needs controlled drug delivery.

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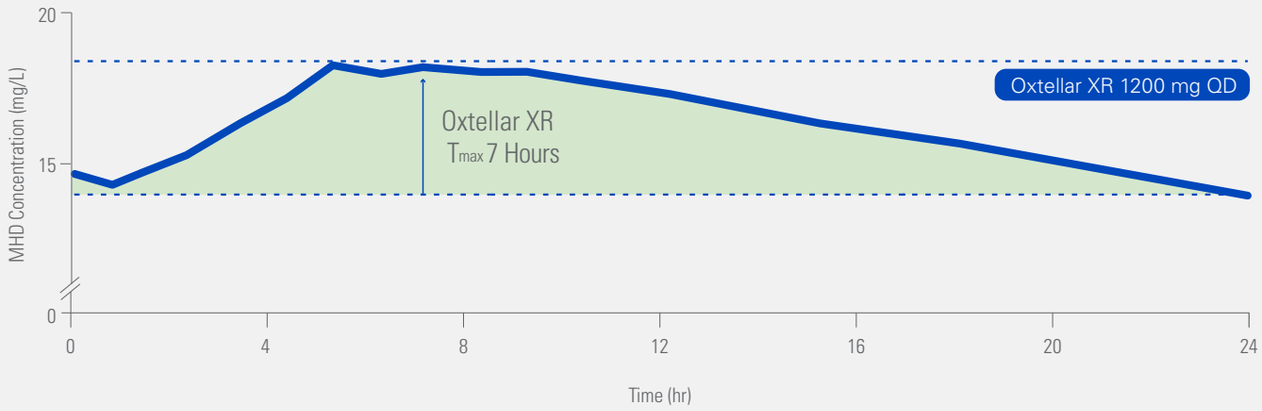
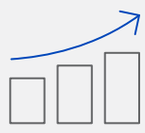
# Steady 24-hour absorption with low fluctuation[1,14]

MHD plasma concentrations in healthy adults at steady state[1,4,14]

**Single-center, multiple-dose, open-label, randomized, 2-treatment crossover study[14]**

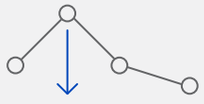



Adapted from data on file, Supernus Pharmaceuticals.



Slow rate of rise[14]

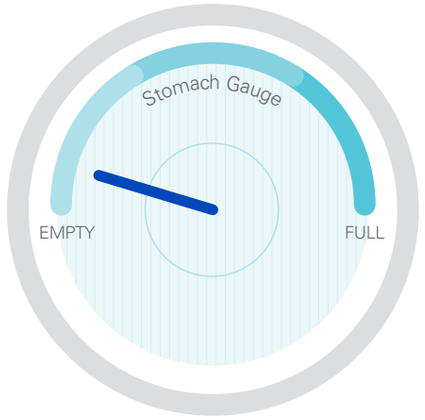
Continued absorption throughout the day[14]



Low peak-to-trough fluctuation[1,14]

Abbreviation: MHD, 10-monohydroxy derivative.

Patients should take Oxtellar XR on an EMPTY STOMACH at least 1 hour before or at least 2 hours after meals.[1]




When Oxtellar XR is taken with food, adverse reactions are more likely to occur because of increased peak plasma concentration levels.[1]



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# He needs controlled drug delivery.

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## Once-daily regimen designed to help patients start and stay with Oxtellar XR

QD dosing with
**3** dosage strengths[1]

Tablets shown are not at actual size.


600 mg 300 mg 150 mg

### Adult Patients[1]

**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]

| WEEK 1 | WEEK 2 |
|---|---|
| 600 | 600 600 |
| 600 mg/day | 1200 mg/day QD at week 2 |

### Pediatric Patients (aged 6 to <17 years)[1]

- Initiate with 8 mg/kg to 10 mg/kg once per day. Titrate to target dose over 2 to 3 weeks. Increase in weekly increments of 8-10 mg/kg once daily, not to exceed 600 mg, to achieve target daily dose

| TARGET DAILY DOSE | WEIGHT |
|---|---|
| 900 mg/day | 20 to 29 kg |
| 1200 mg/day | 29.1 to 39 kg |
| 1800 mg/day | Greater than 39 kg |

### Geriatric Patients[1]

- Start at a lower dosage (300 mg/day or 450 mg/day). Subsequent dosage increases can be made at weekly intervals in increments of 300 mg to 450 mg/day to achieve the desired clinical effect

### Administering Oxtellar XR[1]

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 previously treated with Trileptal® (oxcarbazepine), higher doses of Oxtellar XR may be necessary

See dosing considerations on page 3 for patients with severe renal impairment, taking other AEDs, or taking contraceptives



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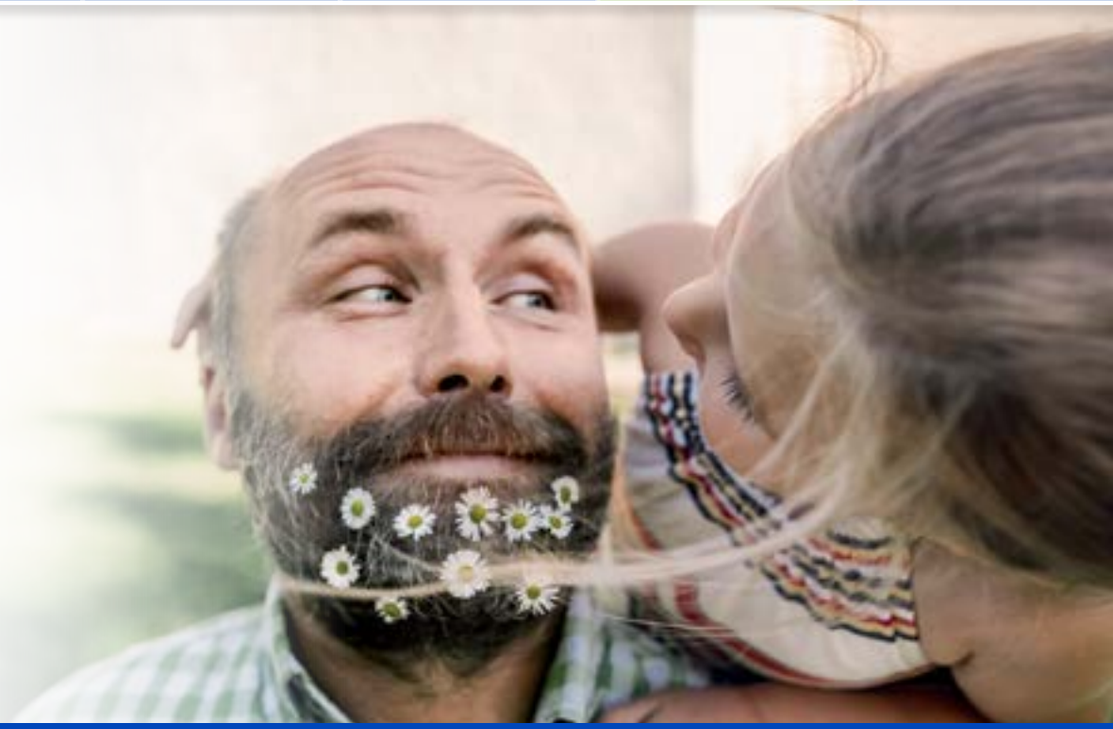
# HELP HENRY WITH HIS GOAL TO BE CLEAR AND IN CONTROL.



Not actual patient. Used for illustrative purposes.

## Make Oxtellar XR your sodium channel blocker of choice for partial-onset seizures

- Powerful evidence for the treatment of partial-onset seizures[2-13]
- Once-daily dosing and a well-characterized safety profile with cognitive AEs similar to placebo[1,4,14]
- 12% of patients in the 2400 mg/day group were seizure free when converted to OXC monotherapy from 1 to 2 AED(s)[2]
- Only 5% of patients discontinued due to AEs in a 12-month add-on OLE study[14] (Please see the OLE study limitations on page 6)

**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.

**References:**
**1.** Oxtellar XR [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc.; December 2018. **2.** Beydoun A, Sachdeo RC, Rosenfeld WE, et al. Oxcarbazepine monotherapy for partial-onset seizures. *Neurology.* 2000;54:2245-2251. **3.** Glauser TA. Oxcarbazepine in the treatment of epilepsy. *Pharmacotherapy.* 2001;21(8):904-919. **4.** French JA, Baroldi P, Brittain ST, Johnson JK; for 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;129:143-153. **5.** Christe W, Krämer G, Vigonius U, Pohlmann H, Steinhoff BJ, Brodie MJ, Moore A. A double-blind controlled clinical trial: oxcarbazepine versus sodium valproate in adults with newly diagnosed epilepsy. *Epilepsy Res.* 1997;26:451-460. **6.** Bill PA, Vigonius U, Pohlman H, Guerreiro CAM, Kochen S, Saffer D, Moore A. *Epilepsy Res.* 1997;27:195-204. **7.** Guerreiro MM, Vigonius U, Pohlman H, de Manreza MLG, Fejerman N, Antoniuk SA, Moore A. A double-blind, controlled clinical trial of oxcarbazepine versus phenytoin in children and adolescents with epilepsy. *Epilepsy Res.* 1997;27:205-213. **8.** Dam M. Oxcarbazepine in monotherapy. *Behav Neurol.* 1990;3(1):31-34. **9.** Sachdeo RC, Beydoun A, Schachter S, et al. Oxcarbazepine (trileptal) as monotherapy in patients with partial seizures. *Neurology.* 2001;57:864-871. **10.** 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. **11.** Schachter SC, Vazquez B, Fisher RS, et al. Oxcarbazepine—double-blind, randomized, placebo controlled, monotherapy trial for partial seizures. *Neurology.* 1999;52:732-737. **12.** Barcs G, Walker EB, Elger CE, Scaramelli A, et al. Oxcarbazepine placebo-controlled, dose-ranging trial in refractory partial epilepsy. *Epilepsia.* 2000;41(12):1597-1607. **13.** Glauser TA, Nigro M, Sachdeo RC, et al. Adjunctive therapy with oxcarbazepine in children with partial seizures. *Neurology.* 2000;54:2237-2254. **14.** Data on file. Supernus Pharmaceuticals, Inc., Rockville, MD. **15.** Johnson J, French JA, Brittain ST, Louro D. Efficacy and tolerability of Oxtellar XR™, a novel, once-daily, extended-release formulation of oxcarbazepine, as adjunctive treatment of refractory partial seizures in a North American subpopulation. Poster presented at: 65th Annual AAN Meeting; March 16-23, 2013. San Diego, CA. **16.** Chung SS, Johnson J, 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.* 2015;133(2):124-130.





Supernus® Pharmaceuticals

# Three monotherapy clinical trials showed powerful seizure reduction in newly diagnosed patients with partial-onset seizures or GTCS*[1-3]

1

## Study 1 Design

A multicenter, randomized, double-blind, placebo-controlled, parallel-group trial consisted of 3 phases: a 56-day baseline during which patients were evaluated for trial eligibility; a 90-day double-blind treatment phase during which patients were randomized to OXC 1200 mg/day (600 mg BID) or placebo; and an OLE phase.[1]

2 & 3

## Study 2 & 3 Design

Two multicenter, randomized, double-blind, parallel group trials evaluated the efficacy and safety of OXC as monotherapy compared to phenytoin (PHT) in epilepsy. Dosing for the study with OXC was flexible between 450-2400 mg/day.[2,3]

**Primary efficacy variable**
Proportion of seizure-free patients who had at least 1 seizure assessment during the maintenance period.[2,3]

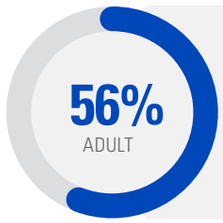
**Primary tolerability variable**
Comparison of patients who prematurely discontinued due to AEs.[2,3]


Partial-onset seizure reduction[1]

STUDY 1

**Of the 32 patients, in total, 3 discontinued OXC treatment prematurely.[1]**

Primary efficacy variable: untreated patients (n=67); analysis of the time to first partial-onset seizure in the ITT population was statistically significant in favor of the OXC group: 12 days (n=32, *P*=0.0457) compared to approximately 3 days in the placebo group (n=35).[1]

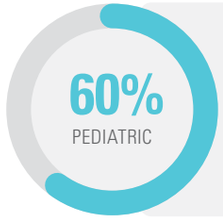



Partial-onset seizure freedom[2]

STUDY 2

**Of the 143 adult patients, in total, 56 discontinued OXC treatment prematurely.[2]**

Adult and adolescent trial of 287 patients, aged 15 to 91 years; 143 OXC and 144 PHT. A majority proportion (59%) of the patients had partial-onset seizures as their main seizure type.[2]




Partial-onset seizure freedom[3]

STUDY 3

**Of the 97 pediatric patients, in total, 24 discontinued OXC treatment prematurely.[3]**

Pediatric trial of 193 children, aged 5 to 17 years; 97 OXC and 96 PHT. A predominant proportion (75%) of the patients had partial-onset seizures as their main seizure type.[3]

*Oxtellar XR is not indicated for treatment of GTCS.

## Did you know?

In a 30-year longitudinal study of 1,795 newly diagnosed patients, only 46% of patients achieved seizure freedom on their first AED. Seizure types were classified according to ILAE guidelines as generalized or focal.[4]

Abbreviations: AEs, adverse events; AEDs, antiepileptic drugs; GTCS, generalized tonic-clonic seizures; ILAE, International League Against Epilepsy; ITT, intent to treat; OLE, open-label extension; OXC, oxcarbazepine; PHT, phenytoin.

**References: 1**. 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. **2**. Bill PA, Vigonius U, Pohlman H, Guerreiro CAM, Kochen S, Saffer D, Moore A. *Epilepsy Res*. 1997;27:195-204. **3**. Guerreiro MM, Vigonius U, Pohlman H, de Manreza MLG, Fejerman N, Antoniuk SA, Moore A. A double-blind, controlled clinical trial of oxcarbazepine versus phenytoin in children and adolescents with epilepsy. *Epilepsy Res*. 1997;27:205-213. **4**. Chen Z, Brodie MJ, Liew D, Kwan P. Treatment outcomes in patients with newly diagnosed epilepsy treated with established and new antiepileptic drugs—a 30-year longitudinal cohort study. *JAMA Neurol*. 2018;75(3):279-286.