Real-World Utilization of Oxtellar XR®:
A Patient Chart Assessment Output


Not actual patient or healthcare provider.

With the aim of providing greater understanding of Oxtellar XR utilization for the treatment of partial-onset seizures, a chart assessment was performed on 519 patients who had been prescribed Oxtellar XR. Oxtellar XR is an extended-release tablet formulation of oxcarbazepine (OXC) indicated for the treatment of partial-onset seizures in patients 6 years of age and older. The survey included a range of patient types that spanned demographic categories and treatment settings. Objectives of the research involved gathering real-world data to elucidate pathways to prescribing Oxtellar XR for partial-onset seizures, including prior therapy regimens, physician drivers of Oxtellar XR use, and patient characteristics that predicted selection of Oxtellar XR.[1]

Data were collected via 40-minute online surveys with epilepsy treaters – neurologists, pediatric neurologists, and epileptologists. Selected treaters were required to spend a minimum of 40% of their professional time in direct patient care and at least half of their professional time in an office or hospital outpatient setting. Additionally, they were required to manage at least 4 patients with partial-onset seizures over the past 6 months and have access to at least 4 patient charts for patients who had received Oxtellar XR in the past 36 months or who were currently taking oxcarbazepine IR, with a prioritization for Oxtellar XR charts.[1]

From these interviews, 150 Oxtellar XR prescribers were recruited for participation. They provided charts from 519 patients who were currently receiving Oxtellar XR.[1]

Larger data sets and prospective studies are needed to confirm observations from this assessment of Oxtellar XR.

The chart assessment revealed that Oxtellar XR was widely prescribed among many of the participating HCPs. In fact, more than one-third (38%) of sampled HCPs prescribed Oxtellar XR to ≥10% of their patients with partial-onset seizures. Additionally, Oxtellar XR was prescribed for a broad range of patients with partial-onset seizures (**Figure 1**).[1]

FIGURE 1. CHARACTERISTICS OF PATIENTS PRESCRIBED OXTELLAR XR[1]

Oxtellar XR patients with partial-onset seizures ranged from 6-83 years of age and the median duration of therapy with Oxtellar XR is about 18 months

54% Male

46% Female

32.5 Average Age (range 6-83)

81% Adult Patients (aged 18+)

19% Pediatric Patients (aged 6-17)

2 Years Average Duration of Treatment With Oxtellar XR (range 3 months-8 years)

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 for complete information on Oxtellar XR, or visit www.OxtellarXRhcp.com and see additional Important Safety Information throughout.

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

The chart assessment also revealed that the majority of participating HCPs selected Oxtellar XR as first- or second-line therapy for their patients with partial-onset seizures (36% and 40%, respectively; **Figure 2**). Oxtellar XR was reserved as a later treatment for only approximately one-fourth of Oxtellar XR patients included in the assessment.[1]

Additionally, HCPs included in this real-world evaluation typically utilized Oxtellar XR as a monotherapy for patients with partial-onset seizures, including those who had failed a prior treatment (**Figure 3**). In fact, approximately 3 of 4 patients prescribed Oxtellar XR in this analysis were receiving it as monotherapy.[1]

Among patients having failed a prior treatment, 71% received Oxtellar XR as a monotherapy.

These interviews provide real-world data for the use of Oxtellar XR in patients with partial-onset seizures. The efficacy and safety of Oxtellar XR are supported by evidence from 11 positive clinical trials of Oxtellar XR/oxcarbazepine IR in both adult and pediatric patients with partial-onset seizures.[2-12]

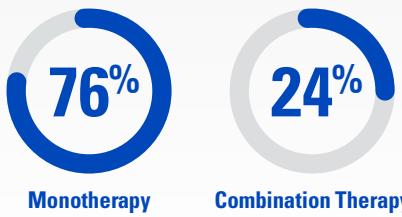
FIGURE 2. OXTELLAR XR TREATMENT PATTERNS – UTILIZATION BY TREATMENT LINE[1]

Oxtellar XR was prescribed as either first- or second-line therapy for the majority (76%) of patients with partial-onset seizures

% of Patients on Oxtellar XR (n=519)

FIGURE 3. OXTELLAR XR TREATMENT PATTERNS – USE AS MONOTHERAPY AND COMBINATION THERAPY[1]

Oxtellar XR was prescribed as monotherapy for most patients with partial-onset seizures, including those who failed a prior treatment



IMPORTANT SAFETY INFORMATION (continued)

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.

Sign up here to receive more information about Oxtellar XR or for access to resources to help manage your patients' partial-onset seizures.

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS & PRECAUTIONS (continued)

- 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 Full Prescribing Information for Oxtellar XR.

References:

1. Data on file. 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™) as adjunctive therapy in patients with refractory partial-onset seizures: a randomized controlled trial. *Acta Neurol Scand.* 2014;129(3):143-153. **3.** Barcs G, Walker EB, Elger CE, et al. Oxcarbazepine placebo-controlled, dose ranging trial in refractory partial epilepsy. *Epilepsia.* 2000;41(12):1597-1607. **4.** Glauser TA, Nigro M, Sachdeo RC, et al. Adjunctive therapy with oxcarbazepine in children with partial seizures. *Neurology.* 2000;54(12):2237-2254. **5.** Christe W, Kramer 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. **6.** 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. **7.** Guerreiro MM, Vigonius U, Pohlman 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. **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(5):864-871. **10.** Sachdeo RC, Edwards K, Hasegawa H, et al. 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 control, monotherapy trial for partial seizures. *Neurology.* 1999;52(4):732-737. **12.** 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.

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