For patients seeking control of their partial-onset seizures,

WHY CHOOSE OXTELLAR XR?

Not actual patient.
Used for illustrative purposes.

INDICATION

Oxtellar XR® is in dicated 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 (on page 3) for complete information on Oxtellar XR, or visit www.OxtellarXRhcp.com.

ONCE-DAILY

Oxtellar XR®

(oxcarbazepine) extended-release tablets

600 mg 300 mg 150 mg

Trusted, proven safe and effective

Oxtellar XR has a well-characterized safety and tolerability to go along with demonstrated efficacy.[1-3]

Supported by 11 positive clinical trials[3-13]

Oxcarbazepine (OXC) Monotherapy Trials: **8**

Oxtellar XR/OXC Adjunctive Therapy Trials: **3**

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 antiepileptic drugs (AEDs) experiencing an average of 6 partial-onset seizures per 28 days, adverse events (AEs) occurring in ≥5% of patients receiving Oxtellar XR with concomitant AEDs and more frequent than with placebo included*,[1,3]:

	Oxtellar XR 2400 mg/day (n=123)	**Oxtellar XR 1200 mg/day** (n=122)	Placebo (n=121)
Dizziness	41%	**20%**	15%
Somnolence	14%	**12%**	9%
Nausea	12%	**12%**	12%
Diplopia	13%	**10%**	4%
Headache	15%	**8%**	7%
Fatigue	3%	**6%**	1%
Vomiting	15%	**6%**	9%
Tremor	1%	**5%**	2%
Balance disorder	7%	**5%**	5%
Asthenia	7%	**3%**	1%

"For oxcarbazepine, this chemical moiety, we have 11 clinical trials, we have a ton of evidence to say 'Yes, this medication can work for partial-onset epilepsy. It's a proven medicine that we know has good documented efficacy.'"

Dr. James Wheless,
BScPharm, MD, FAAP, FACP, FAAN, FAES

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

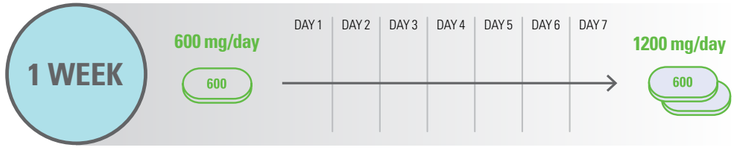
Are your patients experiencing long titration periods?

No patient should have to wait months to reach their optimal treatment dose. Especially when there's a proven, once-daily option with a convenient titration schedule.[1]

Adult patients can reach the 1200 mg/day maintenance dose in just 1 week.*,[1]

1 WEEK to 1200 mg/day

once-daily maintenance dose in adults*,[1]



Once-daily dosing offers patients controlled 24-hour partial-onset seizure medication coverage.[1,2]

*Higher doses may be necessary for some adult patients.

A clear option for your patients with partial-onset seizures

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

- **Similar to placebo[2]**
- **<1% for both 1200 and 2400 mg/day doses[2]**

Please see Important Safety Information (on page 3).

Online sample ordering makes it easy to start with Oxtellar XR

Once patients start, it's easy to stay on with our co-pay and patient assistance programs.

- **$0 co-pay program provides eligible commercially approved patients with free refills for 12 months.***
- **For patients without insurance, Supernus offers a Patient Assistance Program that may be able to help.**

To start patients on Oxtellar XR, scan the QR code for immediate access to our online sample ordering that requires no patient information.

Get started at
www.OxtellarXRhcp.com

OR

Use your mobile device to scan the QR code

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

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.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

References:

1. Oxtellar XR. Package insert. Supernus Pharmaceuticals Inc. **2.** Data on file. 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. **4.** 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. **5.** 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. **6.** 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. **7.** Dam M. Oxcarbazepine in monotherapy. *Behav Neurol.* 1990;3(1):31-34. **8.** 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. **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.** Glauser TA, Nigro M, Sachdeo RC, et al. Adjunctive therapy with oxcarbazepine in children with partial seizures. *Neurology.* 2000;54(12):2237-2254. **13.** Barcs G, Walker EB, Elger CE, et al. Oxcarbazepine placebo-controlled, dose-ranging trial in refractory partial epilepsy. *Epilepsia.* 2000;41(12):1597-1607.

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