## HELP YOUR PATIENTS GET STARTED ON OXTELLAR XR.

Oxtellar XR is an extended-release version of oxcarbazepine that's taken just once daily.<sup>1</sup> As a proven medication that has controlled delivery over 24 hours, it's a powerful choice to help patients with their partial-onset seizure goals.<sup>1-6</sup>

## Why Oxtellar XR?

Powerful evidence for the treatment of partial-onset seizures<sup>3-6</sup> Only FDA-approved AED that provides 24-hour, controlled delivery of oxcarbazepine<sup>1,2</sup>

Once-daily dosing via Solutrol® patented technology<sup>1,2,6</sup>

\$0 co-pay for 12 months for eligible, commercially approved patients\*

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

### Oxtellar XR has 3 dosage strengths to help your patients start on treatment<sup>1</sup>

Once-daily, simple regimen<sup>1</sup>

### Adult

For adult patients with partial-onset seizures<sup>1</sup>

**WEEK 1** 

# WEEK 2

- 1 week to 1200 mg/day once-daily maintenance dose in adults
- 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
- Maintain at 1200 mg/day to 2400 mg/day once daily

Pediatric

For pediatric patients (aged 6 to <17 years) with partial-onset seizures<sup>1</sup>

weight 20-29 kg

TARGET DAILY DOSE

SOO mg/day

**WEIGHT** 29.1-39 kg

TARGET DAILY DOSE

**WEIGHT** 

TARGET DAILY DOSE1800 mg/day

- 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 mg/kg to 10 mg/kg once daily, not to exceed 600 mg, to achieve target daily dose

Geriatric

For geriatric patients with partial-onset seizures<sup>1</sup>

WEEK 1

300 or 450 mg/day

## CAN INCREASE AT WEEKLY INCREMENTS

300-450 mg/day

- 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/day to 450 mg/day to achieve the desired clinical effect

Abbreviation: AED, antiepileptic drug.

### 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 (page 4) for complete information on Oxtellar XR, or visit www.OxtellarXRhcp.com.



## **Considerations for patient counseling**

Let your patients know about the following when starting Oxtellar XR<sup>1</sup>:

Take Oxtellar XR on an EMPTY STOMACH at least 1 hour before or at least 2 hours after meals

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

Take Oxtellar XR tablets whole with water or other liquid. Do not cut, crush, or chew the tablets

- Lower-strength tablets (150 mg tablets) are available for pediatric patients or patients with difficulty swallowing

Use of Oxtellar XR with certain hormonal contraceptives may decrease hormone plasma levels and render these contraceptives less effective

- Additional or alternative nonhormonal forms of contraception are recommended

Common adverse reactions may include the following\*.1:

- Dizziness
- Somnolence
- Headache
- Balance disorder
- Tremor
- Vomiting
- Diplopia
- Asthenia
- Fatigue

Ask your patients to report any side effects that are bothersome or do not go away.

\*The most commonly observed adverse reactions (≥ 5% and more frequent than placebo) seen in adults. Adverse reactions in pediatric patients are similar to those seen in adults. For a complete listing of adverse reactions ≥2%, see full Prescribing Information.

### Considerations for dose modification<sup>1</sup>

For patients previously treated with Trileptal<sup>®</sup> (oxcarbazepine), higher doses of Oxtellar XR may be necessary

Enzyme-inducing antiepileptic drugs such as carbamazepine, phenobarbital, and phenytoin decrease the exposure to 10-monohydroxy derivative, 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



## Do your patients need help paying for Oxtellar XR or getting it approved?

Did you know that 87% of Oxtellar XR commercial claims are approved,<sup>2</sup> meaning you can focus less on paperwork and more on helping patients?



(oxcarbazepine) extended-release tablets

300 mg

150 mg

600 mg

Please refer to the full Prescribing Information and Important Safety Information (page 4) for complete information on Oxtellar XR, or visit www.OxtellarXRhcp.com.

### Oxtellar XR (oxcarbazepine) extended-release tablets for oral use

### **INDICATION**

Oxtellar  $XR^{\oplus}$  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 lifethreatening. 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 ( $\geq$  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:**

Oxtellar XR. Package insert. Supernus Pharmaceuticals Inc; 2018. 2. Data on file. Supernus Pharmaceuticals Inc., Rockville, MD.
 Glauser TA. Oxcarbazepine in the treatment of epilepsy. *Pharmacotherapy*. 2001;21(8):904-919. 4. Glauser TA, Nigro M, Sachdeo RC, et al. Adjunctive therapy with oxcarbazepine in children with partial seizures. *Neurology*. 2000;54(12):2237-2244.
 Barcs G, Walker EB, Elger CE, et al. Oxcarbazepine placebo-controlled, dose-ranging trial in refractory partial epilepsy. *Epilepsia*. 2000;41(12):1597-1607. 6. 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.

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