HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use VIMPAT® safely and effectively. See full prescribing information for VIMPAT.

VIMPAT® (lacosamide) Tablet, Film Coated for Oral use, CV
VIMPAT® (lacosamide) Injection for Intravenous use, CV
VIMPAT® (lacosamide) Oral Solution, CV
Initial U.S. Approval: 2008

----------INDICATIONS AND USAGE----------

VIMPAT is indicated for:

- **Partial-onset seizures (1.1):** Tablets and oral solution are indicated for adjunctive therapy in patients ≥17 years. Injection is indicated as short term replacement when oral administration is not feasible in these patients.

----------DOSAGE AND ADMINISTRATION----------

- **Partial-onset seizures (2.1):** Initially, give 50 mg twice daily (100 mg/day). The dose may be increased, based on clinical response and tolerability, at weekly intervals by 100 mg/day given as two divided doses to a daily dose of 200 to 400 mg/day. VIMPAT injection may be given without further dilution or mixed in compatible diluent and should be administered intravenously over a period of 30 to 60 minutes. **(2.1)**

- **Oral-Intravenous Replacement therapy (2.1):** When switching from oral VIMPAT, the initial total daily intravenous dosage of VIMPAT should be equivalent to the total daily dosage and frequency of oral VIMPAT. At the end of the intravenous treatment period, the patient may be switched to VIMPAT oral administration at the equivalent daily dosage and frequency of the intravenous administration.

  See full prescribing information for compatibility and stability **(2.1)** and dosing in patients with renal impairment **(2.2)** and hepatic impairment **(2.3)**.

----------DOSAGE FORMS AND STRENGTHS----------

- 50 mg (pink), 100 mg (dark yellow), 150 mg (salmon), 200 mg (blue) film-coated tablets **(3)**
- 200 mg/20 mL single-use vial for intravenous use **(3)**
- 10 mg/mL oral solution **(3)**

----------CONTRAINDICATIONS----------

- None

----------WARNINGS AND PRECAUTIONS----------

- Suicidal Behavior and Ideation **(5.1)**
- Patients should be advised that VIMPAT may cause dizziness and ataxia. **(5.2)**
- Caution is advised for patients with known cardiac conduction problems [e.g., second-degree atrioventricular (AV) block], who are taking drugs known to induce PR interval prolongation, or with severe cardiac disease such as myocardial ischemia or heart failure. **(5.3)**
- Patients should be advised that VIMPAT may cause syncope. **(5.4)**
- In patients with seizure disorders, VIMPAT should be gradually withdrawn to minimize the potential of increased seizure frequency. **(5.5)**
- Multiorgan Hypersensitivity Reactions **(5.6)**
- Phenylketonurics **(5.7)**

----------ADVERSE REACTIONS----------

Most common adverse reactions (≥10% and greater than placebo) are diplopia, headache, dizziness, nausea **(6.1)**

To report SUSPECTED ADVERSE REACTIONS, contact UCB, Inc. at 1-800-477-7877 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

----------USE IN SPECIFIC POPULATIONS----------

- To enroll in the UCB AED Pregnancy Registry call 1-888-537-7734 (toll free). To enroll in the North American Antiepileptic Drug Pregnancy Registry call 1-888-233-2334 (toll free). **(8.1)**
- *Renal impairment:* Dose adjustment is recommended for patients with severe renal impairment (creatinine clearance ≤ 30 mL/min). Dose supplementation should be considered following hemodialysis. **(12.3)**
- *Hepatic impairment:* Dose adjustment is recommended for patients with mild or moderate hepatic impairment. Use in severe hepatic impairment patients is not recommended. Patients with co-existing hepatic and renal impairment should be monitored closely during dose titration. **(12.3)**

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide

Revised: 04/2013

FULL PRESCRIBING INFORMATION: CONTENTS*

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Partial-Onset Seizures

VIMPAT (lacosamide) tablets and oral solution are indicated as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older.

VIMPAT (lacosamide) injection for intravenous use is indicated as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older when oral administration is temporarily not feasible.

2 DOSAGE AND ADMINISTRATION

VIMPAT may be taken with or without food.

When using VIMPAT oral solution, it is recommended that a calibrated measuring device be obtained and used. A household teaspoon or tablespoon is not an adequate measuring device. Healthcare

providers should recommend a device that can measure and deliver the prescribed dose accurately, and provide instructions for measuring the dosage.

2.1 Partial-Onset Seizures

VIMPAT can be initiated with either oral or intravenous administration. The initial dose should be 50 mg twice daily (100 mg per day). VIMPAT can be increased at weekly intervals by 100 mg/day given as two divided doses up to the recommended maintenance dose of 200 to 400 mg/day, based on individual patient response and tolerability. In clinical trials, the 600 mg daily dose was not more effective than the 400 mg daily dose, and was associated with a substantially higher rate of adverse reactions. [see *Clinical Studies (14.1)*]

Switching from Oral to Intravenous Dosing

When switching from oral VIMPAT, the initial total daily intravenous dosage of VIMPAT should be equivalent to the total daily dosage and frequency of oral VIMPAT and should be infused intravenously over a period of 30 to 60 minutes. There is experience with twice daily intravenous infusion for up to 5 days.

Switching from Intravenous to Oral Dosing

At the end of the intravenous treatment period, the patient may be switched to VIMPAT oral administration at the equivalent daily dosage and frequency of the intravenous administration.

Compatibility and Stability

VIMPAT injection can be administered intravenously without further dilution or may be mixed with diluents. VIMPAT injection was found to be physically compatible and chemically stable when mixed with the following diluents for at least 24 hours and stored in glass or polyvinyl chloride (PVC) bags at ambient room temperature 15-30°C (59-86°F).

Diluents:

Sodium Chloride Injection 0.9% (w/v)
Dextrose Injection 5% (w/v)
Lactated Ringer's Injection

The stability of VIMPAT injection in other infusion solutions has not been evaluated. Product with particulate matter or discoloration should not be used.

Any unused portion of VIMPAT injection should be discarded.

2.2 Patients with Renal Impairment

No dose adjustment is necessary in patients with mild to moderate renal impairment. A maximum dose of 300 mg/day VIMPAT is recommended for patients with severe renal impairment [creatinine clearance (CL_{CR}) ≤30mL/min] and in patients with endstage renal disease. VIMPAT is effectively removed from plasma by hemodialysis. Following a 4-hour hemodialysis treatment, dosage supplementation of up to 50% should be considered. In all renally impaired patients, the dose titration should be performed with caution. [see *Use in Specific Populations (8.6)*]

2.3 Patients with Hepatic Impairment

The dose titration should be performed with caution in patients with hepatic impairment. A maximum dose of 300 mg/day is recommended for patients with mild or moderate hepatic impairment.

VIMPAT use is not recommended in patients with severe hepatic impairment [see *Use in Specific Populations (8.7)*].

3 DOSAGE FORMS AND STRENGTHS

50 mg (pink), 100 mg (dark yellow), 150 mg (salmon), and 200 mg (blue) film-coated tablets

200 mg/20mL injection

10 mg/mL oral solution

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Suicidal Behavior and Ideation

Antiepileptic drugs (AEDs), including VIMPAT, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Pooled analyses of 199 placebo-controlled clinical trials (mono- and adjunctive therapy) of 11 different AEDs showed that patients randomized to one of the AEDs had approximately twice the risk (adjusted Relative Risk 1.8, 95% CI:1.2, 2.7) of suicidal thinking or behavior compared to patients randomized to placebo. In these trials, which had a median treatment duration of 12 weeks, the estimated incidence of suicidal behavior or ideation among 27,863 AED-treated patients was 0.43%, compared to 0.24% among 16,029 placebo-treated patients, representing an increase of approximately one case of suicidal thinking or behavior for every 530 patients treated. There were four suicides in drug-treated patients in the trials and none in placebo-treated patients, but the number of events is too small to allow any conclusion about drug effect on suicide.

The increased risk of suicidal thoughts or behavior with AEDs was observed as early as one week after starting treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed.

The risk of suicidal thoughts or behavior was generally consistent among drugs in the data analyzed. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5-100 years) in the clinical trials analyzed.

Table 1 shows absolute and relative risk by indication for all evaluated AEDs.

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