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

----------RECENT MAJOR CHANGES----------

Indications and Usage (1)	08/2014
Dosage and Administration (2)	08/2014
Warnings and Precautions (5.3, 5.4)	08/2014

----------INDICATIONS AND USAGE----------
VIMPAT is indicated as monotherapy or adjunctive therapy in patients with partial onset seizures; VIMPAT Injection is indicated as short term replacement when oral administration is not feasible (1)

----------DOSAGE AND ADMINISTRATION----------
- Monotherapy: The initial recommended dose of VIMPAT is 100 mg twice daily; based on individual patient response and tolerability, the dose should be increased at weekly intervals by 50 mg twice daily, up to a recommended maintenance dose of 150 mg to 200 mg twice daily (2.1)

  In patients already taking an antiepileptic drug, the VIMPAT recommended maintenance dose of 150 mg to 200 mg twice daily should be maintained for at least 3 days before initiating withdrawal of the previous antiepileptic drug (2.1)

- Adjunctive Therapy: The initial recommended dose of VIMPAT is 50 mg twice daily; based on individual patient response and tolerability, the dose should be increased at weekly intervals by 50 mg twice daily, up to a recommended maintenance dose of 100 mg to 200 mg twice daily (2.1)

- VIMPAT Injection: VIMPAT Injection must be administered intravenously; when switching from orally administered VIMPAT to VIMPAT Injection, the initial dosing regimen of VIMPAT Injection should be the same as that used for orally administered VIMPAT; VIMPAT Injection can be administered over a period of 15 minutes to 60 minutes; monitor closely patients with known cardiac conduction problems, on concomitant medications that prolong PR interval, or with severe cardiac disease (e.g., myocardial ischemia, heart failure), as VIMPAT may cause bradycardia or AV blocks in these patients (2.2, 5.3)

----------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 (4)

----------WARNINGS AND PRECAUTIONS----------
- Monitor patients for suicidal behavior and ideation (5.1)
- VIMPAT may cause dizziness and ataxia (5.2)
- Cardiac Rhythm and Conduction Abnormalities: ECG before beginning VIMPAT, and after VIMPAT is titrated to steady-state maintenance dose is recommended in patients with known cardiac conduction problems, taking drugs known to induce PR interval prolongation, or with severe cardiac disease (5.3)
- VIMPAT may cause syncope (5.4)
- VIMPAT should be gradually withdrawn to minimize the potential of increased seizure frequency (5.5)
- Multiorgan Hypersensitivity Reactions (5.6)

----------ADVERSE REACTIONS----------
Monotherapy: Most common adverse reactions are similar to those seen in adjunctive therapy studies (6.1)
Adjunctive therapy: 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 1-844-599-2273 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

----------USE IN SPECIFIC POPULATIONS----------
- Pregnancy: Based on animal data, may cause fetal harm (8.1)
- Renal impairment: Dose adjustment is recommended for patients with severe renal impairment (creatinine clearance ≤ 30 mL/min) (2.3, 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 (2.4, 12.3)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide

Revised: 08/2014

FULL PRESCRIBING INFORMATION: CONTENTS*

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

VIMPAT (lacosamide) is indicated in patients 17 years and older with partial-onset seizures as monotherapy or adjunctive therapy.

VIMPAT (lacosamide) injection for intravenous use is an alternative when oral administration is temporarily not feasible.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage for VIMPAT Tablet and Oral solution

Monotherapy

The initial recommended dose of VIMPAT is 100 mg twice daily (200 mg per day); the dose should be increased by 50 mg twice daily (100 mg per day) every week, up to a recommended maintenance dose of 150 mg twice daily to 200 mg twice daily (300 mg to 400 mg per day). Alternatively, VIMPAT may be initiated with a single loading dose of 200 mg, followed approximately 12 hours later by 100 mg twice daily (200 mg per day); this dose regimen should be continued for one week. Based on individual response and tolerability, the dose can be increased at weekly intervals by 50 mg twice daily (100 mg per day), as needed, up to the recommended maintenance dose of 150 mg twice daily to 200 mg twice daily (300 mg to 400 mg per day). The loading dose should be administered with medical supervision because of the increased incidence of CNS adverse reactions [*see Adverse Reactions (6.1) and Clinical Pharmacology (12.3)*].

For patients who are already on a single antiepileptic and will convert to VIMPAT monotherapy, the therapeutic dose of 150 mg twice daily to 200 mg twice daily (300 mg to 400 mg per day) should be

maintained for at least 3 days before initiating withdrawal of the concomitant antiepileptic drug. A gradual withdrawal of the concomitant antiepileptic drug over at least 6 weeks is recommended.

Adjunctive Therapy

The initial recommended dose is 50 mg twice daily (100 mg per day). Based on individual patient response and tolerability, the dose can be increased at weekly intervals by 50 mg twice daily (100 mg per day). The recommended maintenance dose is 100 mg twice daily to 200 mg twice daily (200 mg to 400 mg per day). In clinical trials, the 300 mg twice daily (600 mg per day) dose was not more effective than the 200 mg twice daily dose (400 mg per day), but was associated with a substantially higher rate of adverse reactions [*see Clinical Studies (14.1)*].

Alternatively, VIMPAT may be initiated with a single loading dose of 200 mg, followed approximately 12 hours later by a 100 mg twice daily (200 mg per day); this maintenance dose regimen should be continued for one week. Based on individual patient response and tolerability, the dose can be increased at weekly intervals by 50 mg twice daily (100 mg per day), as needed, up to the maximum recommended maintenance dose of 200 mg twice daily (400 mg per day). The loading dose should be administered with medical supervision because of the increased incidence of CNS adverse reactions [*see Adverse Reactions (6.1) and Clinical Pharmacology (12.3)*]. When discontinuing VIMPAT, a gradual withdrawal over at least 1 week is recommended [*see Warnings and Precautions (5.5)*].

2.2 Dosage for Vimpat Injection

Intravenous VIMPAT can be administered in the same dosing regimens described for oral dosing, including the loading dose. These dosages may be infused intravenously over a period of 15 minutes to 60 minutes. Intravenous infusion of 30 to 60 minutes is preferable, and should be used when a 15 minute administration is not required [*see Clinical Pharmacology (12.3) and Adverse Reactions (6.1)*].

Monitor closely patients with known cardiac conduction problems, on concomitant medications that prolong PR interval, or with severe cardiac disease (e.g., myocardial ischemia, heart failure), as

intravenous infusion of VIMPAT may cause bradycardia or AV blocks in these patients [*see Warnings and Precautions (5.3)].*

When switching from oral to intravenous VIMPAT, the initial total daily intravenous dosage regimen of VIMPAT should be equivalent to the dosage regimen of oral VIMPAT. The clinical study experience of intravenous VIMPAT is limited to 5 days of consecutive treatment. 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.

2.3 Patients with Renal Impairment

No dose adjustment is necessary in patients with mild to moderate renal impairment. A maximum dose of 300 mg per day VIMPAT is recommended for patients with severe renal impairment [creatinine clearance (CL_{CR}) less than or equal to 30 mL/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. Patients with renal impairment who are taking strong inhibitors of CYP3A4 and CYP2C9 may have a significant increase in exposure to VIMPAT. Dose reduction may be necessary in these patients [*see Use in Specific Populations (8.6) and Clinical Pharmacology (12.3)*].

2.4 Patients with Hepatic Impairment

The dose titration should be performed with caution in patients with hepatic impairment. A maximum dose of 300 mg per day is recommended for patients with mild or moderate hepatic impairment. VIMPAT use is not recommended in patients with severe hepatic impairment. Patients with hepatic impairment who are taking strong inhibitors of CYP3A4 and CYP2C9 may have a significant increase in exposure to VIMPAT. Dose reduction may be necessary in these patients [*see Use in Specific Populations (8.7) and Clinical Pharmacology (12.3)*].

2.5 Administration Instructions

VIMPAT may be taken with or without food.

VIMPAT Oral Solution

A calibrated measuring device is recommended to measure and deliver the prescribed dose accurately. A household teaspoon or tablespoon is not an adequate measuring device.

VIMPAT Injection

VIMPAT injection can be administered intravenously without further dilution or may be mixed with diluents listed below. The diluted solution should not be stored for more than 4 hours at room temperature.

Diluents:

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

Product with particulate matter or discoloration should not be used.
Any unused portion of VIMPAT injection should be discarded.

3 DOSAGE FORMS AND STRENGTHS

- 50 mg (pink), 100 mg (dark yellow), 150 mg (salmon), and 200 mg (blue) film-coated tablets
- 200 mg/20 mL injection
- 10 mg/mL oral solution

4 CONTRAINDICATIONS

None.

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