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 (1.1, 1.2)	11/2020
Dosage and Administration (2.1, 2.6)	11/2020
Warnings and Precautions (5.2)	11/2020

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

VIMPAT is indicated for:

- Treatment of partial-onset seizures in patients 4 years of age and older (1.1)
- Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older (1.2)

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

- *Adults (17 years and older):*
  - Initial dosage for monotherapy for the treatment of partial-onset seizures is 100 mg twice daily (2.1)
  - Initial dosage for adjunctive therapy for the treatment of partial-onset seizures or primary generalized tonic-clonic seizures is 50 mg twice daily (2.1)
  - Maximum recommended dosage for monotherapy and adjunctive therapy is 200 mg twice daily (2.1)
- *Pediatric Patients 4 years to less than 17 years*: The recommended dosage is based on body weight and is administered orally twice daily (2.1)
- Increase dosage based on clinical response and tolerability, no more frequently than once per week (2.1)
- Injection: for intravenous use only when oral administration is temporarily not feasible; dosing regimen is the same as oral regimen; administer over 15 to 60 minutes; obtaining ECG before initiation is recommended in certain patients (2.6, 5.3)
- Dose adjustment is recommended for severe renal impairment (2.3, 12.3)
- Dose adjustment is recommended for mild or moderate hepatic impairment; use in patients with severe hepatic impairment is not recommended (2.4, 12.3)

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

- 50 mg, 100 mg, 150 mg, 200 mg tablets (3)
- 200 mg/20 mL single-dose 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: Obtaining ECG before beginning and after titration to steady-state maintenance is recommended in patients with underlying proarrhythmic conditions or on concomitant medications that affect cardiac conduction; closely monitor these patients (5.3, 7.2)
- VIMPAT may cause syncope (5.4)
- VIMPAT should be gradually withdrawn to minimize the potential of increased seizure frequency (5.5)
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/ Multi-Organ Hypersensitivity: Discontinue if no alternate etiology (5.6)

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

- Adjunctive therapy: Most common adverse reactions in adults (≥10% and greater than placebo) are diplopia, headache, dizziness, nausea, and somnolence (6.1)
- Monotherapy: Most common adverse reactions are similar to those seen in adjunctive therapy studies (6.1)
- Pediatric patients: Adverse reactions are similar to those seen in adult patients (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)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide

Revised: 11/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Partial-Onset Seizures

VIMPAT is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

1.2 Primary Generalized Tonic-Clonic Seizures

VIMPAT is indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage Information

The recommended dosage for adults and pediatric patients 4 years to less than 17 years of age is included in Table 1. In pediatric patients 4 years to less than 17 years of age, the recommended dosing regimen is dependent upon body weight. Dosage should be increased based on clinical response and tolerability, no more frequently than once per week. Titration increments should not exceed those shown in Table 1.

Table 1: Recommended Dosage for Adults and Pediatric Patients 4 Years and Older for Partial-Onset Seizures (Monotherapy or Adjunctive Therapy) and Primary Generalized Tonic-Clonic Seizures (Adjunctive Therapy)*

Age and Body Weight	Initial Dosage	Titration Regimen	Maintenance Dosage
Adults (17 years and older)	**Monotherapy**:** 100 mg twice daily (200 mg per day) **Adjunctive Therapy:** 50 mg twice daily (100 mg per day)	Increase by 50 mg twice daily (100 mg per day) every week	**Monotherapy**:** 150 mg to 200 mg twice daily (300 mg to 400 mg per day) **Adjunctive Therapy:** 100 mg to 200 mg twice daily (200 mg to 400 mg per day)
	Alternate Initial Dosage: 200 mg single loading dose, followed 12 hours later by 100 mg twice daily		
Pediatric patients weighing 50 kg or more	50 mg twice daily (100 mg per day)	Increase by 50 mg twice daily (100 mg per day) every week	**Monotherapy**:** 150 mg to 200 mg twice daily (300 mg to 400 mg per day) **Adjunctive Therapy:** 100 mg to 200 mg twice daily (200 mg to 400 mg per day)
Pediatric patients weighing 30 kg to less than 50 kg	1 mg/kg twice daily (2 mg/kg/day)	Increase by 1 mg/kg twice daily (2 mg/kg/day) every week	2 mg/kg to 4 mg/kg twice daily (4 mg/kg/day to 8 mg/kg/day)

Age and Body Weight	Initial Dosage	Titration Regimen	Maintenance Dosage
Pediatric patients weighing 11 kg to less than 30 kg	1 mg/kg twice daily (2 mg/kg/day)	Increase by 1 mg/kg twice daily (2 mg/kg/day) every week	3 mg/kg to 6 mg/kg twice daily (6 mg/kg/day to 12 mg/kg/day)

*when not specified, the dosage is the same for monotherapy for partial-onset seizures and adjunctive therapy for partial-onset seizures or primary generalized tonic-clonic seizures.
**Monotherapy for partial-onset seizures only

In adjunctive clinical trials in adult patients with partial-onset seizures, a dosage higher than 200 mg twice daily (400 mg per day) was not more effective and was associated with a substantially higher rate of adverse reactions *[see Adverse Reactions (6.1) and Clinical Studies (14.2)]*.

VIMPAT Injection Dosage

VIMPAT injection may be used when oral administration is temporarily not feasible *[see Dosage and Administration (2.6) and Warnings and Precautions (5.3)]*. VIMPAT injection can be administered intravenously with the same dosing regimens described for oral dosing.

The clinical study experience of intravenous VIMPAT is limited to 5 days of consecutive treatment.

Loading Dose in Adult Patients (17 Years and Older)

VIMPAT and VIMPAT injection may be initiated in adult patients with a single loading dose of 200 mg, followed approximately 12 hours later by 100 mg twice daily (200 mg per day). This maintenance dose regimen should be continued for one week. VIMPAT can then be titrated as recommended in Table 1. The adult 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)]*.

The use of a loading dose in pediatric patients has not been studied.

2.2 Converting From a Single Antiepileptic (AED) to VIMPAT Monotherapy for the Treatment of Partial-Onset Seizures

For patients who are already on a single AED and will convert to VIMPAT monotherapy, withdrawal of the concomitant AED should not occur until the therapeutic dosage of VIMPAT is achieved and has been administered for at least 3 days. A gradual withdrawal of the concomitant AED over at least 6 weeks is recommended.

2.3 Dosage Information for Patients with Renal Impairment

For patients with mild to moderate renal impairment, no dosage adjustment is necessary.
For patients with severe renal impairment [creatinine clearance (CL_{CR}) less than 30 mL/min as estimated by the Cockcroft-Gault equation for adults; CL_{CR} less than 30 mL/min/1.73m^2 as estimated by the Schwartz equation for pediatric patients] or end-stage renal disease, a reduction of 25% of the maximum dosage is recommended.

In all patients with renal impairment, the dose titration should be performed with caution.

Hemodialysis

VIMPAT is effectively removed from plasma by hemodialysis. Following a 4-hour hemodialysis treatment, dosage supplementation of up to 50% should be considered.

Concomitant Strong CYP3A4 or CYP2C9 Inhibitors

Dose reduction may be necessary in patients with renal impairment who are taking strong inhibitors of CYP3A4 and CYP2C9 *[see Drug Interactions (7.1), Use in Specific Populations (8.6), and Clinical Pharmacology (12.3)]*.

2.4 Dosage Information for Patients with Hepatic Impairment

For patients with mild or moderate hepatic impairment, a reduction of 25% of the maximum dosage is recommended. The dose titration should be performed with caution in patients with hepatic impairment. VIMPAT use is not recommended in patients with severe hepatic impairment.

Concomitant Strong CYP3A4 and CYP2C9 Inhibitors

Dose reduction may be necessary in patients with hepatic impairment who are taking strong inhibitors of CYP3A4 and CYP2C9 *[see Drug Interactions (7.1), Use in Specific Populations (8.7), and Clinical Pharmacology (12.3)]*.

2.5 Administration Instructions for VIMPAT Tablets and Oral Solution

VIMPAT tablets and oral solution may be taken with or without food.

VIMPAT Tablets

VIMPAT tablets should be swallowed whole with liquid. Do not divide VIMPAT tablets.

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 oral solution may also be administered using a nasogastric tube or gastrostomy tube.

Discard any unused VIMPAT oral solution remaining after 7 weeks of first opening the bottle.

2.6 Preparation and Administration Information for VIMPAT Injection

Preparation

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

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Product with particulate matter or discoloration should not be used.

VIMPAT injection is for single-dose only. Any unused portion of VIMPAT injection should be discarded.

Administration

The recommended infusion duration is 30 to 60 minutes; however, infusions as rapid as 15 minutes can be administered in adults if required *[see Adverse Reactions (6.1) and Clinical Pharmacology (12.3)]*. Infusion

durations less than 30 minutes are generally not recommended in pediatric patients *[see Adverse Reactions (6.1)]*.

Intravenous infusion of VIMPAT may cause bradycardia, AV blocks, and ventricular tachyarrhythmia *[see Warnings and Precautions (5.3)]*. Obtaining an ECG before beginning VIMPAT and after VIMPAT is titrated to steady-state maintenance dose is recommended in patients with underlying proarrhythmic conditions or on concomitant medications that affect cardiac conduction *[see Drug Interactions (7.2)]*.

Storage and Stability

The diluted solution should not be stored for more than 4 hours at room temperature. Any unused portion of VIMPAT injection should be discarded.

2.7 Discontinuation of VIMPAT

When discontinuing VIMPAT, a gradual withdrawal over at least 1 week is recommended *[see Warnings and Precautions (5.5)]*.

3 DOSAGE FORMS AND STRENGTHS

VIMPAT Tablets

- 50 mg: pink, oval, film-coated, debossed with "SP" on one side and "50" on the other
- 100 mg: dark yellow, oval, film-coated, debossed with "SP" on one side and "100" on the other
- 150 mg: salmon, oval, film-coated, debossed with "SP" on one side and "150" on the other
- 200 mg: blue, oval, film-coated, debossed with "SP" on one side and "200" on the other

VIMPAT Injection

- 200 mg/20 mL: clear, colorless sterile solution in single-dose vials

VIMPAT Oral Solution

- 10 mg/mL: clear, colorless to yellow or yellow-brown, strawberry-flavored liquid

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

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