STRIKE A BALANCE WHEN STARTING AN AED

START WITH VIMPAT®

Darrell: VIMPAT patient

INDICATION

VIMPAT (lacosamide) Ⓒ is indicated for the treatment of partial-onset seizures in patients 4 years of age and older. As the safety of VIMPAT injection in pediatric patients has not been established, VIMPAT injection is indicated for the treatment of partial-onset seizures only in adult patients (17 years of age and older).

SELECT IMPORTANT SAFETY INFORMATION

VIMPAT is associated with important warnings and precautions including suicidal behavior and ideation, dizziness and ataxia, cardiac rhythm and conduction abnormalities, syncope, and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multi-organ hypersensitivity.

In the adult monotherapy clinical trial, adverse reactions were generally similar to those observed and attributed to drug in adjunctive placebo-controlled trials, with the exception of insomnia (observed at a higher rate of ≥2%). In the adult adjunctive placebo-controlled trials, the most common adverse reactions (≥10% and greater than placebo) were dizziness, headache, nausea, and diplopia. Pediatric adverse reactions were similar to those seen in adult patients.

VIMPAT is a Schedule V controlled substance.

Please see Warnings and Precautions on pages 8 and 9. Please refer to the full Prescribing Information provided by the sales representative, and visit VIMPAThcp.com.

VIMPAT® (lacosamide) Ⓒ

Inspired by **patients.**
Driven by **science.**

EXPANDING OUR COMMITMENT TO EPILEPSY CARE

For patients with partial-onset seizures

VIMPAT® (lacosamide) C IV

IN THE U.S.

2009

Approved for adult **ADJUNCTIVE THERAPY**

2014

Approved for adult **MONOTHERAPY**

2017

Approved for monotherapy and adjunctive therapy in **CHILDREN ≥4 YEARS OF AGE**

Throughout 2017, the refill rate for VIMPAT patients was 80% (n=29,741).[1]

Source: IQVIA Customized Longitudinal Patient Data; 10/2016 – 05/2018.

INDICATION

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ADULT EXPERIENCE

>9

YEARS OF COMMITMENT TO ADULT PATIENTS—AND COUNTING

>400K

ADULT PATIENT EXPOSURES IN THE U.S.[1]

Please see Warnings and Precautions on pages 8 and 9. Please refer to the full Prescribing Information provided by the sales representative, and visit VIMPAThcp.com.

VIMPAT® (LACOSAMIDE) Ⓒ OFFERS AN ESTABLISHED SAFETY AND TOLERABILITY PROFILE IN ADULT PATIENTS[2]

ADVERSE EVENTS (AEs) PROFILE

ADVERSE EVENTS WERE GENERALLY OBSERVED TO BE MILD TO MODERATE IN CLINICAL TRIALS

Partial-Onset Seizure Placebo-controlled Adjunctive Trials:

Most common AEs (%) for ≥10% of total VIMPAT-treated patients and greater than placebo*

AE	PLACEBO (n=364)	VIMPAT 200 mg/day (n=270)	VIMPAT 400 mg/day (n=471)
Dizziness	8	16	30
Headache	9	11	14
Nausea	4	7	11
Diplopia	2	6	10

*Patients in these clinical trials were treated with 1 to 3 concomitant AEDs.

In placebo-controlled adjunctive trials, the most common adverse reactions were dizziness, headache, nausea, and diplopia. In the historical-control monotherapy trial, adverse reactions were generally similar to those observed in the adjunctive trials, with the exception of insomnia.

The majority of adverse reactions were generally mild to moderate and were generally dose related.

Please see Warnings and Precautions on pages 8 and 9. Please refer to the full Prescribing Information provided by the sales representative, and visit VIMPAThcp.com.

	MOST COMMON ADVERSE REACTIONS DURING TITRATION[2]:	DISCONTINUATION RATES DUE TO ADVERSE EVENTS[2]:
Adjunctive Therapy Trials:	dizziness	8% at 200 mg/day, 17% at 400 mg/day
Monotherapy Trial:	dizziness, headache, nausea, somnolence, and fatigue	16% at 300 mg/day to 400 mg/day

Adverse reactions with IV administration generally appeared similar to those observed with the oral formulation, although IV administration was associated with local adverse events, such as injection site pain or discomfort (2.5%), irritation (1%), and erythema (0.5%).

SELECT IMPORTANT SAFETY INFORMATION

Adverse Reactions

Adjunctive therapy: In the adult placebo-controlled clinical trials, the most frequently seen adverse reaction with VIMPAT was dizziness (31% vs 8% placebo). Other common adverse reactions occurring in ≥10 percent of VIMPAT-treated patients, and greater than placebo, were headache, nausea, and diplopia.

Monotherapy: In the adult clinical trial, adverse reactions were generally similar to those observed and attributed to drug in adjunctive placebo-controlled trials, with the exception of insomnia (occurred at a higher rate of ≥2%).

VIMPAT® PHARMACOKINETIC (PK) DRUG INTERACTIONS AND PHARMACODYNAMICS IN ADULTS

CLINICALLY RELEVANT PK INTERACTIONS WITH OTHER DRUGS ARE UNLIKELY[2]

- VIMPAT exhibits low plasma protein binding (<15%)
- Not an enzyme inducer

IN VIMPAT STUDIES, NO KNOWN CLINICALLY RELEVANT PK DRUG–DRUG INTERACTIONS WERE IDENTIFIED

No clinically relevant PK drug-drug interactions were observed with the below commonly prescribed antiepileptic drugs (AEDs) and additional medications that are frequently used for conditions such as diabetes and GERD, and for patients at risk for blood clots.†

AEDs			
Carbamazepine	Lamotrigine	Phenobarbital	Valproic Acid
Clonazepam	Levetiracetam*	Phenytoin	Zonisamide
Gabapentin	Oxcarbazepine	Topiramate	

Other medications studied		
Digoxin	Omeprazole	Oral contraceptives (0.03 mg ethinylestradiol/ 0.15 mg levonorgestrel)
Metformin	Warfarin	
Midazolam		

*Levetiracetam is a product manufactured by UCB.
†Does not rule out the possibility of pharmacodynamic interactions.

Please see Warnings and Precautions on pages 8 and 9.
Please refer to the full Prescribing Information provided by the sales representative, and visit VIMPAThcp.com.

CLINICALLY RELEVANT PHARMACODYNAMIC INTERACTIONS[2]

Because of a risk of AV block, bradycardia, or ventricular tachyarrhythmia, VIMPAT should be used with caution in patients on medications that prolong PR interval (including sodium channel blocking AEDs), and concomitant medications that affect cardiac conduction, including:

- sodium channel blockers
- beta-blockers
- calcium channel blockers
- potassium channel blockers

In such patients, obtaining an ECG before beginning VIMPAT, and after VIMPAT is titrated to steady-state, is recommended. In addition, these patients should be closely monitored if they are administered VIMPAT through the intravenous route. Patients should be made aware of and report cardiac signs or symptoms to their healthcare provider right away.

Dosage adjustments are recommended for patients with mild or moderate hepatic impairment or severe renal impairment. Use in patients with severe hepatic impairment is not recommended. Dose titration should be performed with caution in all patients with renal and/or hepatic impairment.

Patients with hepatic or renal impairment taking strong inhibitors of CYP3A4 or CYP2C9 may have a significant increase in exposure to VIMPAT. Dose reduction may be necessary in these patients.

Caution should be exercised for dose titration in elderly patients.

SELECT IMPORTANT SAFETY INFORMATION

Cardiac Rhythm and Conduction Abnormalities

PR Interval Prolongation, Atrioventricular Block, and Ventricular Tachyarrhythmia

Dose-dependent prolongations in PR interval with VIMPAT have been observed in clinical studies in adult patients and in healthy volunteers. When VIMPAT is given with other drugs that prolong the PR interval, further PR prolongation is possible.

In the postmarketing setting, there have been reports of cardiac arrhythmias in patients treated with VIMPAT, including bradycardia, AV block, and ventricular tachyarrhythmia, which have rarely resulted in asystole, cardiac arrest, and death. Most, although not all, cases have occurred in patients with underlying proarrhythmic conditions, or in those taking concomitant medications that affect cardiac conduction or prolong the PR interval. These events have occurred with both oral and intravenous routes of administration and at prescribed doses as well as in the setting of overdose.

VIMPAT® WARNINGS AND PRECAUTIONS

Antiepileptic drugs (AEDs), including VIMPAT, increase the risk of suicidal behavior and ideation

Pooled analyses of 199 placebo-controlled clinical trials of 11 different AEDs showed that patients randomized to one of the AEDs had approximately twice the risk of suicidal thinking or behavior compared to patients randomized to placebo.

Monitor patients for the emergence or worsening of depression; unusual changes in mood or behavior; or suicidal thoughts, behavior, or self-harm.

Advise patients, their caregivers, and/or families to be alert for these changes and report them immediately to a healthcare provider.

VIMPAT may cause dizziness and ataxia

In adult clinical trials, the onset of dizziness and ataxia was most commonly observed during titration.

Advise patients not to drive, operate complex machinery, or engage in other hazardous activities until they are familiar with the effects of VIMPAT.

Dizziness and ataxia were also observed in pediatric clinical trials.

Cardiac Rhythm and Conduction Abnormalities

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VIMPAT should be used with caution in patients with underlying proarrhythmic conditions such as known cardiac conduction problems (e.g., marked first-degree AV block, second-degree or higher AV block and sick sinus syndrome without pacemaker), severe cardiac disease (such as myocardial ischemia or heart failure, or structural heart disease), and cardiac sodium channelopathies (e.g., Brugada Syndrome).

VIMPAT should also be used with caution in patients on concomitant medications that affect cardiac conduction, including sodium channel blockers, beta-blockers, calcium channel blockers, potassium channel blockers, and medications that prolong the PR interval. In such patients, obtaining an ECG before beginning VIMPAT, and after VIMPAT is titrated to steady-state maintenance dose, is recommended. In addition, these patients should be closely monitored if they are administered VIMPAT through the intravenous route. Patients should be made aware of and report cardiac signs or symptoms to their healthcare provider right away.

Atrial Fibrillation and Atrial Flutter

VIMPAT administration may predispose to atrial arrhythmias (atrial fibrillation or flutter), especially in patients with diabetic neuropathy and/or cardiovascular disease.

Syncope

VIMPAT may cause syncope in adult and pediatric patients.

Withdrawal of Antiepileptic Drugs

Gradually withdraw VIMPAT (over a minimum of 1 week) to minimize the potential of increased seizure frequency.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

Also known as multi-organ hypersensitivity, has been reported with antiepileptic drugs, including VIMPAT. Some of these events have been fatal or life-threatening. If signs or symptoms are present, immediately evaluate the patient. Discontinue VIMPAT if an alternative etiology for the signs and symptoms cannot be established.

Risks in Patients with Phenylketonuria

VIMPAT oral solution contains aspartame, a source of phenylalanine, which can be harmful in patients with phenylketonuria (PKU).

A 200 mg dose of VIMPAT oral solution (equivalent to 20 mL) contains 0.32 mg of phenylalanine.

VIMPAT is a Schedule V controlled substance.

Please refer to the full Prescribing Information provided by the sales representative, and visit VIMPAThcp.com.

For more information on VIMPAT® contact 844-599-CARE (2273).

STRIKE A BALANCE WHEN STARTING AN AED IN YOUR ADULT PARTIAL-ONSET (FOCAL) SEIZURE PATIENTS

VIMPAT (lacosamide) Ⓒ is indicated for the treatment of partial-onset seizures in patients 4 years of age and older. As the safety of VIMPAT injection in pediatric patients has not been established, VIMPAT injection is indicated for the treatment of partial-onset seizures only in adult patients (17 years of age and older).

VIMPAT offers an ESTABLISHED SAFETY AND TOLERABILITY PROFILE

- The most common AEs in the placebo-controlled adjunctive trials were dizziness, headaches, nausea, and diplopia. Adverse reactions observed in the monotherapy trial were generally similar, with the exception of insomnia
- Adverse events were generally observed to be mild to moderate in clinical trials

In VIMPAT studies, NO KNOWN CLINICALLY RELEVANT PHARMACOKINETIC DRUG–DRUG INTERACTIONS were identified

CLINICALLY RELEVANT PHARMACODYNAMIC INTERACTIONS CAN OCCUR in patients on concomitant medications that affect cardiac conduction or prolong the PR interval

- In these patients, ECG monitoring is recommended (please see pages 8 and 9 for more information).

Please see Warnings and Precautions on pages 8 and 9. Please refer to the full Prescribing Information provided by the sales representative, and visit VIMPAThcp.com.

VIMPAT is AVAILABLE IN MULTIPLE FORMULATIONS—including tablets, oral solution, and injection—with a simple 1:1 dose conversion

VIMPAT IS COVERED BY 95% OF COMMERCIAL PLANS[1]

- 3 out of 4 commercially insured patients paid $20 or less per 30-day supply of VIMPAT with the VIMPAT Savings Program[1]

SELECT IMPORTANT SAFETY INFORMATION

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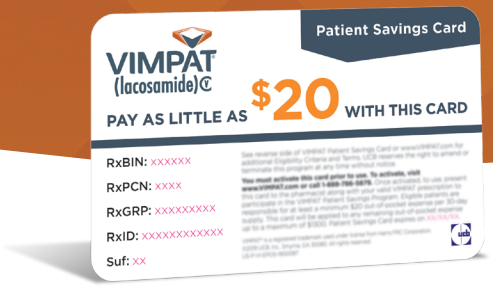
UCB IS COMMITTED TO MAKING TREATMENT ACCESSIBLE

>95%

OF COMMERCIAL AND MEDICAID PATIENTS HAVE FORMULARY ACCESS TO VIMPAT® (LACOSAMIDE) Ⓒ, AND MOST HAVE UNRESTRICTED ACCESS[1]



WE'RE ALSO COMMITTED TO **MAKING TREATMENT AFFORDABLE**

Nearly 75% of eligible commercial patients* paid as little as $20 per 30-day supply of VIMPAT® with the VIMPAT Patient Savings Program[1]

* Patients are responsible for a minimum of $20 out-of-pocket expense per 30-day supply. This card will be applied to any remaining out-of-pocket expense up to a maximum of $1300. When you use this card, you are certifying that you meet the complete Eligibility Criteria and Terms and that you have not submitted, and will not submit, a claim for reimbursement under any federal, state or other governmental programs for this prescription. If you have any questions regarding the VIMPAT Patient Savings Program or wish to discontinue your participation, please call 1-888-786-5879 (8:30 am – 5:30 pm ET, Monday – Friday and 8:30 am – 2 pm ET, Saturday). This savings card is not valid for use by patients who are covered by any federally funded or state-funded healthcare program (including, but not limited to, Medicare [Part D and Medigap] and those who are Medicare-eligible and enrolled in an employer sponsored health plan for retirees, Medicaid, any state pharmaceutical assistance program, TRICARE, VA, or DoD), or for cash-paying patients. Offer good only in the U.S., including Puerto Rico. This card is good for use only with a valid VIMPAT prescription consistent with the approved FDA labeling at the time the prescription is filled by the pharmacist and dispensed to the patient. The maximum annual benefit amount is $1300 per calendar year. Void where prohibited by law, taxed, or restricted. This offer cannot be combined with any other promotional offer. UCB, Inc. reserves the right to rescind, revoke, or amend this offer without notice at any time. No cash value. Not eligible for sale, purchase, trade, or counterfeit.

References:

1. Data on file. UCB, Inc.
2. VIMPAT® (lacosamide): US prescribing information. Smyrna (GA): UCB, Inc.

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