

WHEN WOULD YOUR PATIENTS WANT A FULL THERAPEUTIC DOSE?



BRIVIACT® (brivaracetam) © THE ONE THAT STARTS DAY ONE¹

BRIVIACT is indicated for the treatment of partial-onset (focal) seizures in patients 4 years of age and older.

As the safety of BRIVIACT injection in pediatric patients has not been established, BRIVIACT injection is indicated for the treatment of partial-onset seizures only in adult patients (16 years of age and older).

IMPORTANT SAFETY INFORMATION

BRIVIACT is associated with important warnings and precautions including suicidal behavior and ideation, somnolence, fatigue, dizziness, disturbance in gait and coordination, psychiatric adverse reactions including non-psychotic and psychotic symptoms, and hypersensitivity reactions (bronchospasm and angioedema). BRIVIACT is contraindicated in patients with a prior hypersensitivity reaction to brivaracetam or any of the inactive ingredients.

In adult adjunctive therapy placebo-controlled clinical trials, the most common adverse reactions (at least 5% for BRIVIACT and at least 2% more frequently than placebo) were somnolence and sedation, dizziness, fatigue, and nausea and vomiting symptoms. Adverse reactions reported in clinical studies of pediatric patients 4 years to less than 16 years of age were generally similar to those in adult patients.

BRIVIACT is a Schedule V controlled substance.

For additional Important Safety Information, see pages 8-9. Please refer to the full Prescribing Information provided in the back pocket, and visit www.BRIVIACTHCP.com.

BRIVIACT® is a new molecular entity in the racetam class that targets SV2A

IN A PRECLINICAL DISCOVERY PROGRAM, THE AFFINITY OF RACETAM ANALOGS FOR SYNAPTIC VESICLE PROTEIN 2A (SV2A) STRONGLY CORRELATED TO THEIR ANTICONVULSANT ACTIVITY IN AN ANIMAL MODEL²⁻⁴

The most promising compounds were profiled in a broad range of animal models of seizures and epilepsy^{2,3}

Agents with an animal model profile similar to levetiracetam* were not pursued through Phase III clinical trials³



BRIVIACT displayed anticonvulsant activity in numerous animal models of seizures and epilepsy including classical screening models^{2,3}



BRIVIACT® 
(brivaracetam) 

BRIVIACT displays a high and selective affinity for SV2A in the brain, which may contribute to the anticonvulsant effect¹

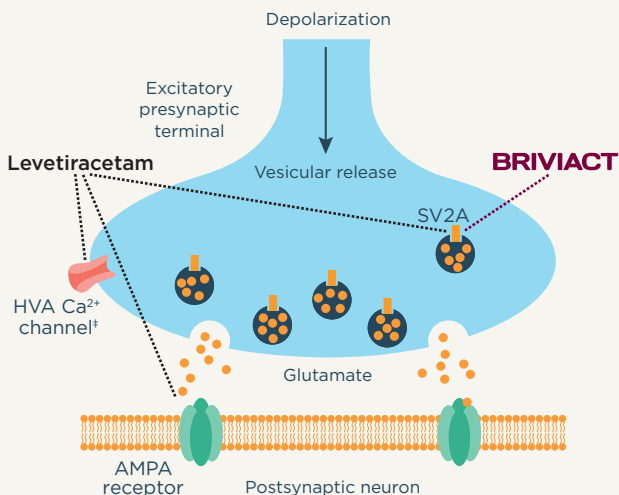
The precise mechanism by which BRIVIACT exerts its anticonvulsant activity is unknown¹

*Levetiracetam is a product manufactured by UCB.

IMPORTANT SAFETY INFORMATION

Suicidal Behavior and Ideation: Antiepileptic drugs, including BRIVIACT, increase the risk of suicidal behavior and ideation. Monitor patients taking BRIVIACT 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 behavioral changes and report them immediately to a healthcare provider.

**SV2A BINDING IS PROPOSED TO BE THE
PRIMARY MECHANISM OF ACTION (MOA) FOR
BRIVIACT® AND LEVETIRACETAM^{††3-9}**



- Based on in vitro studies:
 - BRIVIACT displays a 15- to 30-fold higher affinity for SV2A¹⁰
 - BRIVIACT does not display activity at HVA Ca²⁺ channels[†] or AMPA receptors³
- Implications for clinical efficacy and tolerability are not known

*The precise mechanism by which levetiracetam exerts its anticonvulsant activity is unknown.

†Not all proposed mechanisms of levetiracetam are depicted.

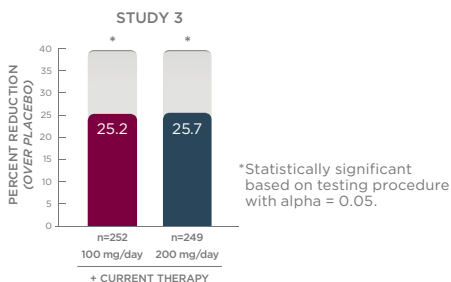
‡High-voltage-activated calcium channel.

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Please refer to the full Prescribing Information provided in
the back pocket, and visit www.BRIVIACTHCP.com.**

Adult efficacy was established in trials that did not utilize a titration period

Adult efficacy was demonstrated in patients with partial-onset seizures and has been extrapolated for children ages 4 and older according to FDA guidelines.

PERCENT REDUCTION OVER PLACEBO IN PARTIAL-ONSET SEIZURE FREQUENCY ADJUSTED TO 28 DAYS DURING THE TREATMENT PERIOD¹



- Effectiveness was established in 3 fixed-dose, randomized, double-blind, placebo-controlled, multicenter studies, which included 1550 patients
- Enrolled patients had partial-onset seizures that were not adequately controlled by 1 to 2 concomitant antiepileptic drugs (AEDs)

BRIVIACT[®] was studied in a challenging adult patient population

Baseline Characteristics of Patients in Study 3¹¹

Median seizure frequency at baseline	Seizures per 28 days	10
AEDs discontinued prior to trial enrollment	0-1 AEDs	19%
	2-4 AEDs	34%
	5 or more AEDs	47%

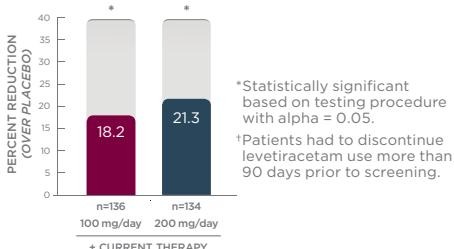
IMPORTANT SAFETY INFORMATION

Neurological Adverse Reactions: BRIVIACT causes somnolence, fatigue, dizziness, and disturbance in coordination. Somnolence and fatigue-related adverse reactions were reported in 25% of patients taking at least 50 mg per day of BRIVIACT compared to 14% of patients taking placebo. Dizziness and disturbance in gait and coordination were reported in 16% of patients taking at least 50 mg per day of BRIVIACT compared to 10% of patients taking placebo. The risk is greatest early in treatment but can occur at any time. Monitor patients for these signs and symptoms and advise them not to drive or operate machinery until they have gained sufficient experience on BRIVIACT.

Efficacy was observed among adult patients taking BRIVIACT® who had previously discontinued levetiracetam

PERCENT REDUCTION OVER PLACEBO IN PARTIAL-ONSET SEIZURE FREQUENCY ADJUSTED TO 28 DAYS DURING THE TREATMENT PERIOD¹¹

STUDY 3: Patients with Prior Levetiracetam Exposure



- In Study 3, approximately 54% of patients had prior exposure to levetiracetam and were evaluated in a pre-specified analysis^{+1,11}
 - Of prior levetiracetam patients, approximately 68% had failed levetiracetam due to efficacy, 14% had discontinued for an adverse drug reaction, and 20% had discontinued for other reasons¹¹
- Adult patients taking concomitant levetiracetam were excluded from the study¹

Adult patients with prior levetiracetam exposure presented with more severe baseline characteristics

Baseline Characteristics of Patients with Prior Levetiracetam Exposure in Study 3¹¹

Median seizure frequency at baseline	Seizures per 28 days	12
AEDs discontinued prior to trial enrollment	0-1 AEDs	4%
	2-4 AEDs	22%
	5 or more AEDs	74%

For additional Important Safety Information, see pages 8-9. Please refer to the full Prescribing Information provided in the back pocket, and visit www.BRIVIACTHCP.com.

BRIVIACT® offers adult patients a therapeutic dose on DAY ONE

The recommended starting dose for monotherapy and adjunctive therapy in adult patients (16 years and older) is 50 mg twice daily (100 mg/day) and is initiated without titration.¹

START WITH A THERAPEUTIC DOSE



50 MG TWICE A DAY (100 MG/DAY)



(Products not shown at actual size)

Gradual dose escalation is not required with BRIVIACT

- Based on individual patient response, the dose may be adjusted between 25 mg twice daily (50 mg/day) and 100 mg twice daily (200 mg/day)
- Avoid abrupt withdrawal from BRIVIACT in order to minimize the risk of increased seizure frequency and status epilepticus

Dosing in Specific Adult Populations¹

Impairment	Dose Recommendations
Hepatic Impairment Mild, moderate, and severe	Recommended Starting Dose: 25 mg twice daily (50 mg/day) Recommended Maximum Dose: 75 mg twice daily (150 mg/day)
Renal Impairment	<ul style="list-style-type: none">• Dose adjustments are not required for patients with impaired renal function• There are no data in patients with end-stage renal disease undergoing dialysis, and use of BRIVIACT is not recommended in this patient population

IMPORTANT SAFETY INFORMATION

Psychiatric Adverse Reactions: BRIVIACT causes psychiatric adverse reactions, including non-psychotic and psychotic symptoms. These events were reported in approximately 13% of patients taking at least 50 mg per day of BRIVIACT compared to 8% of patients taking placebo. A total of 1.7% of adult patients taking BRIVIACT discontinued treatment due to psychiatric reactions compared to 1.3% of patients taking placebo. Advise patients to report these symptoms immediately to a healthcare provider.

BRIVIACT® is available in multiple formulations, allowing for dosing flexibility in adult patients (16 years and older)



**Injection solution
50 mg/5 mL:**

Single-use vial for undiluted injection or infusion



Tablets*:
60-count bottles

*10-mg tablets are available for down titration.



**Oral solution
10 mg/mL:**

300-mL bottles

(Products not shown at actual size)

As the safety of BRIVIACT injection in pediatric patients has not been established, BRIVIACT injection is indicated for the treatment of partial-onset seizures only in adult patients (16 years of age and older).

Considerations for using BRIVIACT formulations in adult patients¹

- BRIVIACT can be given with or without food
- BRIVIACT tablets should be swallowed whole with liquid; they should not be chewed or crushed
- BRIVIACT injection may be used when oral administration is temporarily not feasible
- BRIVIACT injection should be administered intravenously over 2 to 15 minutes, clinical study experience is limited to 4 consecutive days of treatment
- No blood-level monitoring required
- Oral solution should be stored at room temperature

The most common adverse reactions (at least 5% for BRIVIACT and at least 2% more frequently than placebo) are somnolence and sedation, dizziness, fatigue, and nausea and vomiting symptoms. Adverse reactions with BRIVIACT injection are generally similar to those observed with BRIVIACT tablets and also include dysgeusia, euphoric mood, feeling drunk, and infusion site pain.

For additional Important Safety Information, see pages 8-9. Please refer to the full Prescribing Information provided in the back pocket, and visit www.BRIVIACTHCP.com.

BRIVIACT® safety information

WARNINGS AND PRECAUTIONS¹

Antiepileptic drugs, including BRIVIACT, increase the risk of suicidal behavior and ideation

- 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

Causes somnolence, fatigue, dizziness, and disturbance in gait and coordination

- Somnolence and fatigue-related adverse reactions reported in 25% of patients taking at least 50 mg per day of BRIVIACT compared to 14% of patients taking placebo
- Dizziness and disturbance in gait and coordination reported in 16% of patients taking at least 50 mg per day of BRIVIACT compared to 10% of patients taking placebo
- Risk is greatest early in treatment but can occur at any time
- Monitor patients and advise them not to drive or operate machinery until they have sufficient experience on BRIVIACT

Causes psychiatric adverse reactions, including non-psychotic and psychotic symptoms

- Events reported in approximately 13% of patients taking at least 50 mg per day of BRIVIACT compared to 8% of patients taking placebo
- 1.7% of adult patients taking BRIVIACT discontinued treatment due to psychiatric reactions compared to 1.3% of patients taking placebo
- Psychiatric adverse reactions were also observed in open-label pediatric trials and were generally similar to those observed in adults
- Advise patients to report these symptoms immediately to a healthcare provider

Can cause hypersensitivity reactions; bronchospasm and angioedema have been reported

- Discontinue BRIVIACT if a patient develops a hypersensitivity reaction after treatment
- Contraindicated in patients with prior hypersensitivity to brivaracetam or any of the inactive ingredients in BRIVIACT

Withdrawal of antiepileptic drugs

- As with all antiepileptic drugs, BRIVIACT should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus

BRIVIACT is a Schedule V controlled substance.

Safety and tolerability of BRIVIACT® were evaluated without utilizing a titration period

In adult adjunctive placebo-controlled trials, the most common adverse reactions (at least 5% for BRIVIACT and at least 2% more frequently than placebo) are¹:

- Somnolence and sedation
- Dizziness
- Fatigue
- Nausea and vomiting

ADULT ADVERSE REACTIONS THAT OCCURRED AT LEAST 2% MORE FREQUENTLY FOR BRIVIACT DOSES OF AT LEAST 50 MG/DAY THAN PLACEBO IN POOLED PLACEBO-CONTROLLED ADJUNCTIVE THERAPY STUDIES¹

Adverse Reactions		BRIVIACT (n=803) %	Placebo (n=459) %
Gastrointestinal disorders	Nausea/vomiting	5	3
	Constipation	2	0
Nervous system disorders	Somnolence and sedation	16	8
	Dizziness	12	7
	Fatigue	9	4
	Cerebellar coordination and balance disturbances*	3	1
Psychiatric disorders	Irritability	3	1

*Cerebellar coordination and balance disturbances include ataxia, balance disorder, coordination abnormal, and nystagmus.

There was no apparent dose-dependent increase in adverse reactions with the exception of somnolence and sedation¹

Most adverse events in trials were reported to be mild to moderate¹¹

Across all 3 trials, discontinuation rates due to adverse events were¹:

- Placebo: 4%
- BRIVIACT 50 mg/day: 5%
- BRIVIACT 100 mg/day: 8%
- BRIVIACT 200 mg/day: 7%

The most common adverse reaction leading to discontinuation was dizziness¹¹

The safety profile of BRIVIACT in pediatric patients 4 years of age and older with partial-onset seizures is based upon open-label trials, and was similar to the safety profile in adult patients with partial-onset seizures.

Please refer to the full Prescribing Information provided in the back pocket, and visit www.BRIVIACTHCP.com.

BRIVIACT® offers a therapeutic dose on DAY ONE

In pediatric patients 4 years to less than 16 years of age, the recommended dosing regimen is dependent upon body weight and is only recommended to be administered orally. When initiating treatment, gradual dose escalation is not required.

RECOMMENDED DOSAGE FOR PEDIATRIC PATIENTS 4 TO <16 YEARS

Body Weight	Initial Dosage	Minimum and Maximum Maintenance Dosage
≥50 kg	50 to 100 mg/day (25 to 50 mg BID)	50 to 200 mg/day (25 to 100 mg BID)
20 kg to <50 kg	1 to 2 mg/kg/day (0.5 to 1 mg/kg BID)	1 to 4 mg/kg/day (0.5 to 2 mg/kg BID)
11 kg to <20 kg	1 to 2.5 mg/kg/day (0.5 to 1.25 mg/kg BID)	1 to 5 mg/kg/day (0.5 to 2.5 mg/kg BID)

Dosage should be adjusted based on clinical response and tolerability.

- As the safety of BRIVIACT injection in pediatric patients has not been established, BRIVIACT injection is indicated for the treatment of partial-onset seizures only in adult patients (16 years of age and older).
- Avoid abrupt withdrawal from BRIVIACT in order to minimize the risk of increased seizure frequency and status epilepticus.

Select dosing in special populations

- Renal impairment: Dose adjustments are not required for patients with impaired renal function. There are no data in patients with end-stage renal disease undergoing dialysis, and use of BRIVIACT is not recommended in this patient population.
- Hepatic impairment: For all stages of hepatic impairment, the recommended starting dosage for adults and pediatric patients weighing 50 kg or more is 25 mg twice daily (50 mg per day), and the recommended maximum dosage is 75 mg twice daily (150 mg per day). The recommended starting dosage for pediatric patients with hepatic impairment weighing 11 kg to less than 50 kg is 0.5 mg/kg twice daily (1 mg/kg per day). The maximum dosage for pediatric patients with hepatic impairment weighing 20 kg to less than 50 kg is 1.5 mg/kg twice daily (3 mg/kg per day). The maximum dosage for pediatric patients with hepatic impairment weighing 11 kg to less than 20 kg is 2 mg/kg twice daily (4 mg/kg per day).

For flexibility in administration, BRIVIACT® offers two formulations for pediatric patients (4 to <16 years) with partial-onset seizures



Oral solution
10 mg/mL:

300-mL bottles

Simple 1:1



Dose Conversion



Tablets*:

60-count bottles

*10-mg tablets are also available.

(Products not shown at actual size)

As the safety of BRIVIACT injection in pediatric patients has not been established, BRIVIACT injection is indicated for the treatment of partial-onset seizures only in adult patients (16 years of age and older).

Considerations for using BRIVIACT formulations¹

- BRIVIACT can be given with or without food.
- BRIVIACT tablets should be swallowed whole with liquid; they should not be chewed or crushed.
- No blood-level monitoring required.
- Oral solution should be stored at room temperature.

IMPORTANT SAFETY INFORMATION

In adult adjunctive therapy placebo-controlled trials, the most common adverse reactions (at least 5% for BRIVIACT and at least 2% more frequently than placebo) were somnolence and sedation, dizziness, fatigue, and nausea and vomiting symptoms. Adverse reactions reported in clinical studies of pediatric patients 4 years to less than 16 years of age were generally similar to those seen in adult patients.

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Drug interactions

General Drug Interactions¹

Rifampin

- Co-administration with rifampin decreases BRIVIACT® plasma concentrations likely because of CYP2C19 induction
- Increase the BRIVIACT dosage in patients on concomitant rifampin by up to 100% (i.e., double the dosage)

BRIVIACT and Other AEDs¹

None of the interactions listed below requires changes in the dose of BRIVIACT, but interactions with carbamazepine and phenytoin can be clinically important

Carbamazepine

- Co-administration may increase exposure to carbamazepine-epoxide (active metabolite)
- Available data did not reveal any safety concerns, but dose reduction should be considered if tolerability issues arise

Phenytoin

- BRIVIACT can increase plasma concentration of phenytoin
- Monitor levels of phenytoin during co-administration

Levetiracetam

- BRIVIACT had no added therapeutic benefit when co-administered

IMPORTANT SAFETY INFORMATION

Hypersensitivity: BRIVIACT can cause hypersensitivity reactions. Bronchospasm and angioedema have been reported. Discontinue BRIVIACT if a patient develops a hypersensitivity reaction after treatment. BRIVIACT is contraindicated in patients with a prior hypersensitivity reaction to brivaracetam or any of the inactive ingredients.

Withdrawal of Antiepileptic Drugs: As with all antiepileptic drugs, BRIVIACT should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus.

BRIVIACT[®] exhibits a linear and a time-independent pharmacokinetic profile

Pharmacokinetics of brivaracetam are similar when used as monotherapy or adjunctive therapy for treatment of partial-onset seizures¹

Pharmacokinetic Profile of BRIVIACT¹

Absorption

- Highly permeable and rapidly and almost completely absorbed after oral administration
- Median t_{\max} is 1 hour after oral dose
- Absolute bioavailability is ~100%

Distribution

- Low levels of plasma protein binding ($\leq 20\%$)
- Rapidly, evenly distributed in most tissues
- Volume of distribution similar to total body water (0.5 L/kg)

Metabolism

- Extensively metabolized
- No pharmacologically active metabolite
- Primarily mediated by hydrolysis
- Secondarily mediated by CYP2C19 hydroxylation and by CYP2C9 hydrolysis

Elimination

- $t_{1/2}$ is 9 hours; steady state is reached after ~2 days
- >95% of dose excreted in urine
- <10% of active drug excreted in urine

For additional Important Safety Information, see pages 8-9. Please refer to the full Prescribing Information provided in the back pocket, and visit www.BRIVIACTHCP.com.

Joel is concerned that his uncontrolled partial-onset (focal) seizures are interrupting his teaching career



MEDICAL HISTORY

36 years old; diagnosed with partial-onset seizures 18 years ago



PREVIOUS AED THERAPY

Phenytoin



CURRENT THERAPY

Lamotrigine 600 mg/day



CURRENT PRESENTATION

Intermittent partial-onset seizures, 3 per week



EXPECTATIONS

Further seizure control to avoid time away from the classroom

For additional Important Safety Information, see pages 8-9. Please refer to the full Prescribing Information provided in the back pocket, and visit www.BRIVIACTHCP.com.

IMPORTANT SAFETY INFORMATION

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BRIVIACT® provides a therapeutic dose, right from the start

THERAPEUTIC DOSE ON DAY ONE

BRIVIACT offers a therapeutic dose on DAY ONE¹

- Gradual dose escalation is not required

TARGETS SV2A

BRIVIACT is a new molecular entity that targets SV2A¹

- Based on in vitro studies, BRIVIACT displays a 15- to 30-fold higher affinity for SV2A¹⁰; implications for clinical efficacy and tolerability are not known
- The precise mechanism by which BRIVIACT exerts its anticonvulsant activity is unknown¹

ESTABLISHED EFFICACY

The efficacy of BRIVIACT was established in 3 fixed-dose, randomized, double-blind, placebo-controlled, multicenter studies, which included 1550 patients¹

- In Study 3, approximately 54% of patients had prior exposure to levetiracetam and were evaluated in a pre-specified analysis^{1,11}
- In the pre-specified analysis of patients with prior levetiracetam exposure, efficacy over placebo was observed among patients taking BRIVIACT¹¹

SAFETY AND TOLERABILITY

Safety and tolerability of BRIVIACT were established without utilizing a titration period¹

- Most common adverse reactions are somnolence and sedation, dizziness, fatigue, and nausea and vomiting symptoms

For additional Important Safety Information, see pages 8-9. Please refer to the full Prescribing Information provided in the back pocket, and visit www.BRIVIACTHCP.com.

Help minimize out-of-pocket costs for your eligible patients

ELIGIBLE BRIVIACT PATIENTS MAY PAY AS LITTLE AS \$10 PER 30-DAY SUPPLY OF BRIVIACT® (brivaracetam) ©

Have them present the BRIVIACT Patient Savings Card to the pharmacy when filling their prescription. Eligibility restrictions and terms apply.

To learn more about card setup, claim transmission, patient eligibility, and more, call OPUS Health for the BRIVIACT Patient Savings Program at 1-888-786-5879 (8:30 AM to 5:30 PM, Eastern time, Monday–Friday, and 8:30 AM to 2 PM, Eastern time, Saturday).

Please see eligibility criteria on the back of the patient savings card.



For more information on the BRIVIACT Patient Savings Program, please visit www.BRIVIACT.com.

References: 1. BRIVIACT (brivaracetam): US prescribing information. Smyrna (GA): UCB, Inc. 2. Matagne A, Margineanu DG, Kenda B, Michel P, Klitgaard H. Anti-convulsive and anti-epileptic properties of brivaracetam (ucb 34714), a high-affinity ligand for synaptic vesicle protein, SV2A. *Br J Pharmacol*. 2008;154(8):1662-1671. 3. Klitgaard H, Matagne A, Nicolas JM, et al. Brivaracetam: Rationale for discovery and preclinical profile of selective SV2A ligand for epilepsy treatment. *Epilepsia*. 2016;57(4):538-548. 4. Noyer M, Gillard M, Matagne A, Hénichart J-P, Wülfert E. The novel antiepileptic drug levetiracetam (ucb L059) appears to act via a specific binding site in CNS membranes. *Eur J Pharmacol*. 1995;286:137-146. 5. Yan HD, Ishihara K, Seki T, et al. Inhibitory effects of levetiracetam on the high-voltage-activated L-type Ca^{2+} channels in hippocampal CA3 neurons of spontaneously epileptic rat (SER). *Brain Res Bull*. 2013;90:142-148. 6. Niespodziany I, Klitgaard H, Margineanu DG. Levetiracetam inhibits the high-voltage-activated $Ca(2+)$ current in pyramidal neurons of rat hippocampal slices. *Neurosci Lett*. 2001;306(1-2):5-8. 7. Lukyanetz EA, Shkryl VM, Kostyuk PG. Selective blockade of N-type calcium channels by levetiracetam. *Epilepsia*. 2002;43(1):9-18. 8. Carunchio I, Pieri M, Ciotti MT, Albo F, Zona C. Modulation of AMPA receptors in cultured cortical neurons induced by the antiepileptic drug levetiracetam. *Epilepsia*. 2007;48(4):654-662. 9. Rigo JM, Nguyen L, Hans G, et al. UCB 34714: effect on inhibitory and excitatory neurotransmission. *Epilepsia*. 2004;45(3):56. 10. Gillard M, Fuks B, Leclercq K, Matagne A. Binding characteristics of brivaracetam, a selective, high affinity SV2A ligand in rat, mouse and human brain: Relationship to anti-convulsant properties. *Eur J Pharmacol*. 2011;664(1-3):36-44. 11. Data on file. UCB, Inc.