Fycompa™ (perampanel) TABLETS 2•4•6•8•10•12 mg ORAL SUSPENSION 0.5 mg/mL

FYCOMPA® (perampanel) is indicated in patients with epilepsy aged 4 years and older for partial-onset seizures (POS) with or without secondarily generalized seizures and adjunctive therapy for patients aged 12 years and older for primary generalized tonic-clonic (PGTC) seizures.

CONSIDER **FYCOMPA®** WHEN

Treating Convulsive Seizures

- **Partial-onset seizures that secondarily generalize**
  Monotherapy or adjunctive therapy for patients ≥4 years of age
- **Primary generalized tonic-clonic (PGTC) seizures**
  Adjunctive therapy for patients ≥12 years of age

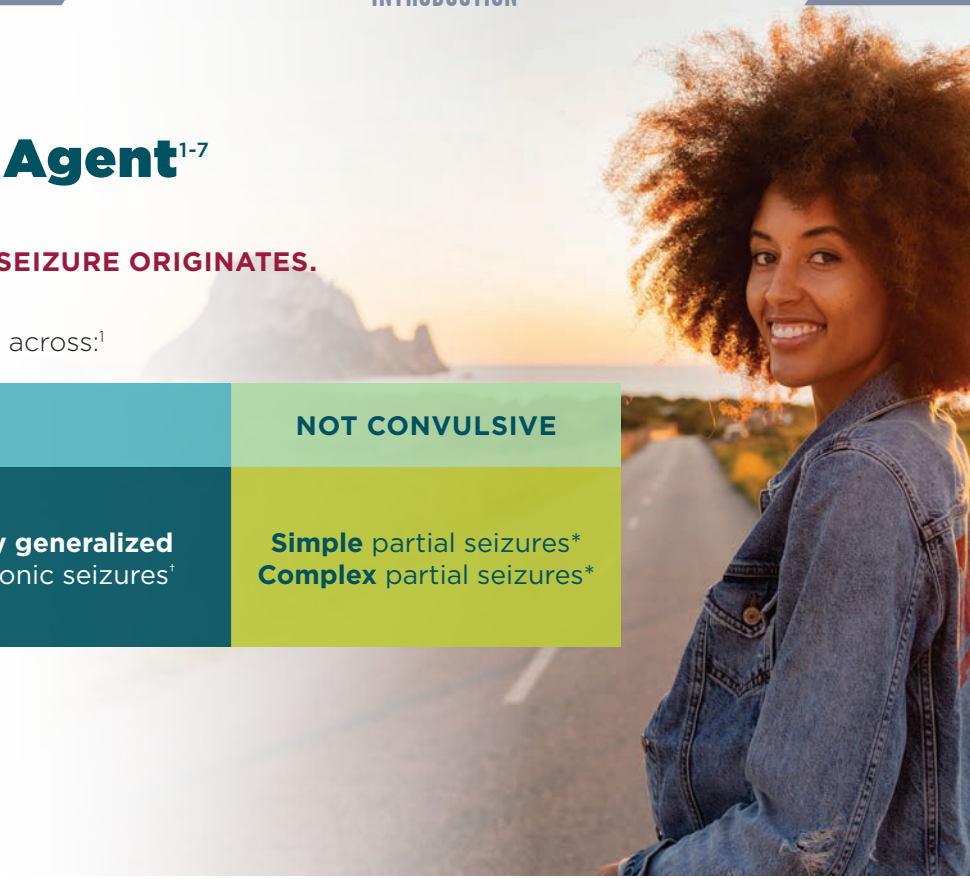
SELECTED SAFETY INFORMATION

Please see Important Safety Information throughout and complete **Boxed WARNING** relating to serious or life-threatening psychiatric and behavioral adverse reactions including aggression, hostility, irritability, anger, homicidal ideation, and threats which may occur in patients with and without prior psychiatric history, prior aggressive behavior, or concomitant use of medications associated with hostility and aggression.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

ONCE-DAILY FYCOMPA®

A Broad-Spectrum Agent[1-7]



WE DON'T ALWAYS KNOW WHERE A SEIZURE ORIGINATES.

FYCOMPA offers potential seizure control across:[1]

CONVULSIVE		NOT CONVULSIVE
Partial-onset seizures that **secondarily generalize***	**Primary generalized** tonic-clonic seizures†	**Simple** partial seizures* **Complex** partial seizures*

*Adjunctive therapy or monotherapy for patients ≥4 years of age.
†Adjunctive therapy for patients ≥12 years of age.

SELECTED SAFETY INFORMATION

WARNING: SERIOUS PSYCHIATRIC AND BEHAVIORAL REACTIONS

- Serious or life-threatening psychiatric and behavioral adverse reactions including aggression, hostility, irritability, anger, and homicidal ideation and threats have been reported in patients taking FYCOMPA
- These reactions occurred in patients with and without prior psychiatric history, prior aggressive behavior, or concomitant use of medications associated with hostility and aggression
- Advise patients and caregivers to contact a healthcare provider immediately if any of these reactions or changes in mood, behavior, or personality that are not typical for the patient are observed while taking FYCOMPA or after discontinuing FYCOMPA
- Closely monitor patients particularly during the titration period and at higher doses
- FYCOMPA should be reduced if these symptoms occur and should be discontinued immediately if symptoms are severe or are worsening

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

Straightforward Titration

- **Add once-daily FYCOMPA** to any ASM.[8,*]
- **No blood monitoring** required.[1]
- Contraindications: **None.**[1]

IN PARTIAL-ONSET SEIZURES (WITH OR WITHOUT SECONDARY GENERALIZATION)

Efficacy may be seen as early as 4 mg.[1,9]

1. **Start patients at 2 mg once daily at bedtime.** Increase the dose gradually, letting *at least* a week pass between 2 mg dose increases. Slower titration may be preferred for some patients, based on clinical response and tolerability.[1,†]
2. **Assess at 4 mg.** Some patients with partial-onset seizures may respond to a 4 mg dose, which can be achieved in as little as 2 weeks.[1,9,†]
3. **Adjust as necessary.** Modify dose as needed based on individual clinical response and tolerability.[1]

*In population PK analysis, FYCOMPA did not have clinically significant effects on other ASMs. When prescribing, keep in mind that:
- FYCOMPA may decrease the efficacy of contraceptives containing levonorgestrel.
- FYCOMPA plasma levels were decreased when administered with moderate and strong CYP3A4 inducers, including carbamazepine, phenytoin, or oxcarbazepine.
- Use of FYCOMPA with CNS depressants, including alcohol, may increase CNS depression.

†The recommended maintenance dose range for partial-onset seizures is 8 mg to 12 mg once daily.

SELECTED SAFETY INFORMATION

SERIOUS PSYCHIATRIC AND BEHAVIORAL REACTIONS

In the partial-onset seizures clinical trials, hostility- and aggression-related adverse reactions occurred in 12% and 20% of patients randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 6% of patients in the placebo group. These effects were dose-related and generally appeared within the first 6 weeks of treatment, although new events continued to be observed through more than 37 weeks. These effects in FYCOMPA-treated patients led to dose reduction, interruption, and discontinuation more frequently than placebo-treated patients. Homicidal ideation and/or threat have also been reported postmarketing in patients treated with FYCOMPA. The combination of alcohol and FYCOMPA significantly worsened mood and increased anger. Patients taking FYCOMPA should avoid the use of alcohol. Patients, their caregivers, and families should be informed that FYCOMPA may increase the risk of psychiatric events. Patients should be monitored during treatment and for at least one month after the last dose of FYCOMPA, and especially when taking higher doses and during the initial few weeks of drug therapy (titration period) or at other times of dose increases. Similar serious psychiatric and behavioral events were observed in the primary generalized tonic-clonic (PGTC) seizure clinical trial.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

Straightforward Titration

- **Add once-daily FYCOMPA** to any ASM.[8,*]
- **No blood monitoring** required.[1]
- Contraindications: **None.**[1]

IN PRIMARY GENERALIZED TONIC-CLONIC SEIZURES[1]

1. **Start patients at 2 mg once daily at bedtime.** Increase the dose gradually, letting *at least* a week pass between 2 mg dose increases. Slower titration may be preferred for some patients, based on clinical response and tolerability.[1,†]

2. **Adjust as necessary.** Modify dose as needed based on individual clinical response and tolerability.[1]

*In population PK analysis, FYCOMPA did not have clinically significant effects on other ASMs. When prescribing, keep in mind that:
- FYCOMPA may decrease the efficacy of contraceptives containing levonorgestrel.
- FYCOMPA plasma levels were decreased when administered with moderate and strong CYP3A4 inducers, including carbamazepine, phenytoin, or oxcarbazepine.
- Use of FYCOMPA with CNS depressants, including alcohol, may increase CNS depression.

†The recommended maintenance dose for primary generalized tonic-clonic seizures is 8 mg once daily.

SELECTED SAFETY INFORMATION

SERIOUS PSYCHIATRIC AND BEHAVIORAL REACTIONS

In the partial-onset seizures clinical trials, hostility- and aggression-related adverse reactions occurred in 12% and 20% of patients randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 6% of patients in the placebo group. These effects were dose-related and generally appeared within the first 6 weeks of treatment, although new events continued to be observed through more than 37 weeks. These effects in FYCOMPA-treated patients led to dose reduction, interruption, and discontinuation more frequently than placebo-treated patients. Homicidal ideation and/or threat have also been reported postmarketing in patients treated with FYCOMPA. The combination of alcohol and FYCOMPA significantly worsened mood and increased anger. Patients taking FYCOMPA should avoid the use of alcohol. Patients, their caregivers, and families should be informed that FYCOMPA may increase the risk of psychiatric events. Patients should be monitored during treatment and for at least one month after the last dose of FYCOMPA, and especially when taking higher doses and during the initial few weeks of drug therapy (titration period) or at other times of dose increases. Similar serious psychiatric and behavioral events were observed in the primary generalized tonic-clonic (PGTC) seizure clinical trial.

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FYCOMPA® OFFERS

Once-daily Dosing at Bedtime

IN PARTIAL-ONSET SEIZURES (WITH OR WITHOUT SECONDARY GENERALIZATION)[1]

FYCOMPA tablets. Not actual sizes.

1. Increase dose gradually by 2 mg increments, using weekly intervals at a minimum. **Longer intervals may be more appropriate for your patient**, depending on individual clinical response and tolerability.[1]

2. **Assess at 4 mg.** Some patients with partial-onset seizures may respond at 4 mg.[1,9,†]

When dosing FYCOMPA Oral Suspension, simply **double the tablet dose in mg to get the dose in mL** (example: 6 mg = 12 mL).[1]

If your patient is taking moderate or strong CYP3A4 inducers: Starting dose is **4 mg**.[1,†]

12 mg is the highest dose studied.[‡]

For pediatric patients (aged 4 years and older), **dosing is not based on weight.**[12]

*In POS patients, a dose of 12 mg once daily resulted in somewhat greater reductions in seizure rates than the dose of 8 mg once daily, but with a substantial increase in adverse reactions.

†Closely monitor patients when starting or withdrawing moderate or strong CYP3A4 inducers (including enzyme-inducing ASMs such as carbamazepine, phenytoin, and oxcarbazepine). Dose adjustment may be necessary.

‡For patients taking enzyme-inducing agents, a maintenance dose has not been established. Individual dose should be titrated to clinical response and tolerability.

SELECTED SAFETY INFORMATION

SUICIDAL BEHAVIOR AND IDEATION

Antiepileptic drugs (AEDs), including FYCOMPA, increase the risk of suicidal thoughts or behavior in patients. Anyone considering prescribing FYCOMPA or any other AED must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Patients, their caregivers, and families should be informed of the risk and advised to monitor and immediately report the emergence or worsening of depression, suicidal thoughts or behavior, thoughts about self-harm and/or any unusual changes in mood or behavior. Should suicidal thoughts and behavior emerge during treatment, consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

FYCOMPA® OFFERS

Once-daily Dosing at Bedtime

PRIMARY GENERALIZED TONIC-CLONIC SEIZURES[1]

FYCOMPA tablets. Not actual sizes.

Start at			Recommended maintenance dose based on pivotal trials		
2 mg	4 mg	6 mg	8 mg*	10 mg	12 mg

1. Increase dose gradually by 2 mg increments, using weekly intervals at a minimum. **Longer intervals may be more appropriate for your patient**, depending on individual clinical response and tolerability.

When dosing FYCOMPA Oral Suspension, simply **double the tablet dose in mg to get the dose in mL** (example: 6 mg = 12 mL).[1]

If your patient is taking moderate or strong CYP3A4 inducers: Starting dose is **4 mg**.[1,†]

12 mg is the highest dose studied.[‡]

For pediatric patients (aged 12 years and older), **dosing is not based on weight.**[12]

*In primary generalized tonic-clonic seizure patients, 8 mg is the recommended maintenance dose. Patients who are tolerating FYCOMPA at 8 mg once daily and require further reduction of seizures may benefit from a dose increase up to 12 mg once daily if tolerated.

†Closely monitor patients when starting or withdrawing moderate or strong CYP3A4 inducers (including enzyme-inducing ASMs such as carbamazepine, phenytoin, and oxcarbazepine). Dose adjustment may be necessary.

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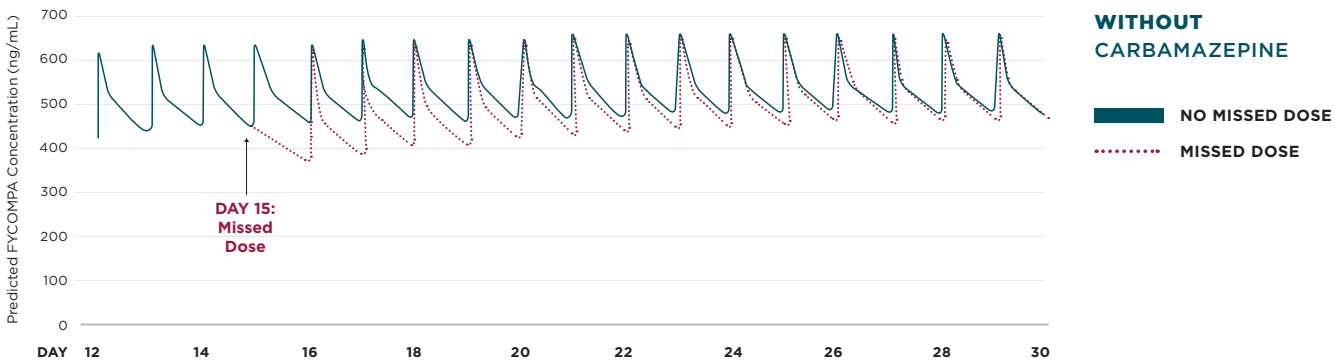
FYCOMPA® HAS A LONG HALF-LIFE OF UP TO 105 HOURS[1,*]

What If Your Patient Misses a Dose?

PLASMA LEVELS REMAIN RELATIVELY STABLE.[13]

No makeup dose required—if only one dose is missed, your patient can get back on track the next day.[1,†]



LIMITATION:

PK model not prospectively carried out in patients; further studies needed to replicate findings[13]

DESIGN:

Simulated PK model based on parameters derived from 19 Phase I FYCOMPA trials conducted in adults (N=606)[13]

- Non-linear mixed effects modeling
- Simulations performed for patients receiving FYCOMPA 8 mg/day

*Established in Phase I clinical trials with healthy adults. In pediatric patients ages 4-11, the half-life of FYCOMPA is long but is reduced by approximately half.[12] In the presence of concomitant moderate or strong CYP3A4 inducers, FYCOMPA continues to have a long half-life but it is reduced by approximately half in both adults and pediatrics.[12]

†Patients who miss a dose should resume dosing the following day at their prescribed dose.[1]

Instruct patients to contact their physician if more than one day of dosing is missed.

SELECTED SAFETY INFORMATION

DIZZINESS AND GAIT DISTURBANCE

FYCOMPA caused dose-related increases in events related to dizziness and disturbance in gait or coordination. Dizziness and vertigo were reported in 35% and 47% of patients in the partial-onset seizure trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 10% of placebo-treated patients. Gait disturbance related events were reported in 12% and 16% of patients in the partial-onset seizure clinical trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 2% of placebo-treated patients. These adverse reactions occurred mostly during the titration phase. These adverse reactions were also observed in the PGTC seizure clinical trial.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

FYCOMPA® HAS A LONG HALF-LIFE OF UP TO 105 HOURS[1,*]

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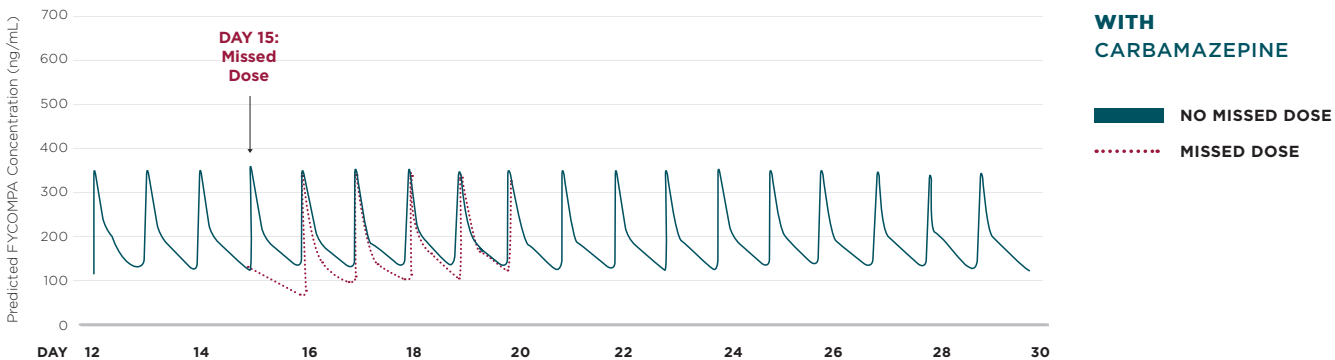

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A UNIQUE MOA

The First and Only Non-Competitive AMPA Receptor Antagonist

Glutamate is the primary neurotransmitter regulating excitatory synaptic transmission in the brain, and FYCOMPA® is the only ASM with AMPA glutamate receptor activity as its therapeutic target.* FYCOMPA:

- Is specifically engineered to block glutamate activity at postsynaptic AMPA receptors.[1]
- Potentially targets hyperexcitatory neurotransmission by inhibiting AMPA glutamate receptor activity.[1]

A different MOA could mean a different approach.

*The precise mechanism by which FYCOMPA exerts its antiepileptic effects in humans is unknown.

SELECTED SAFETY INFORMATION

SOMNOLENCE AND FATIGUE

FYCOMPA caused dose-dependent increases in somnolence and fatigue-related events. Somnolence was reported in 16% and 18% of patients in the partial-onset seizure trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 7% of placebo-treated patients. Fatigue-related events were reported in 12% and 15% of patients in the partial-onset seizure trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 5% of placebo-treated patients. These adverse reactions occurred mostly during the titration phase. These adverse reactions were also observed in the PGTC seizure clinical trial. Patients should be advised against engaging in hazardous activities requiring mental alertness, such as operating motor vehicles or dangerous machinery, until the effect of FYCOMPA is known. Patients should be carefully observed for signs of central nervous system (CNS) depression when FYCOMPA is used with other drugs with sedative properties because of potential additive effects.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

THE FYCOMPA® INSTANT SAVINGS CARD

Savings of Up to $1,300 per Year*

With the FYCOMPA Instant Savings Card:

*The FYCOMPA Instant Savings Card Program is not available to patients enrolled in Federal or state healthcare programs, including Medicare, Medicaid, Medigap, VA, DoD, or TRICARE. Depending on the insurance plan, patients could have additional financial responsibility for any amounts over Catalyst Pharmaceuticals' maximum liability. See https://www.fycompa.com/savings-card for full terms/conditions. Eligible cash patients can receive up to $60 per prescription for a maximum savings of $720 per year.

FYCOMPA® Access and Patient Support

92% **of FYCOMPA prescriptions** presented in a pharmacy are dispensed.*

We're ready to assist your office with access and reimbursement.

*IMS Plan Trak (FIA) data current as of January 2020.

Catalyst Pharmaceuticals cannot guarantee payment of any claim. Coding, coverage, and reimbursement may vary significantly by payor, plan, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payors following receipt of claims. For additional information, customers should consult with their payors for all relevant coding, reimbursement, and coverage requirements. It is the sole responsibility of the provider to select the proper code and ensure the accuracy of all claims used to seek reimbursement. All services must be medically appropriate and properly supported in the patient medical record.

FYCOMPA® AT APPROVAL

Pivotal Trials for Partial-Onset Seizures Were Conducted With Refractory Patients

PATIENTS HAD 9 TO 14 SEIZURES IN 4 WEEKS AT BASELINE, DESPITE TAKING UP TO 3 ASMs.[1,*]

FYCOMPA received approval based on 3 clinical trials in patients with uncontrolled partial-onset seizures.[1,*] During the 6-week titration period:

- >85% took 2 to 3 concomitant ASMs.[1]
- Patients were titrated up on a fixed schedule, and randomized to one of the maintenance doses studied.[9,10,11,†]
- Only patients experiencing intolerable adverse reactions were permitted a dose reduction.[1,‡]

*Median number of seizures per 28 days. >85% took 2 to 3 concomitant ASMs yet still had 9 to 14 partial-onset seizures a month.[1] Approximately 50% were taking at least 1 ASM known to induce CYP3A4 (eg, carbamazepine, oxcarbazepine, or phenytoin).[1]

†Once-daily perampanel at 8 mg or 12 mg (Study 304 and Study 305) or at 2 mg, 4 mg, or 8 mg (Study 306).[9,10,11]

‡According to the investigators' clinical judgment.

SELECTED SAFETY INFORMATION

FALLS

Falls were reported in 5% and 10% of patients in the partial-onset seizure clinical trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 3% of placebo-treated patients.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

INTRODUCTION
PARTIAL-ONSET SEIZURES

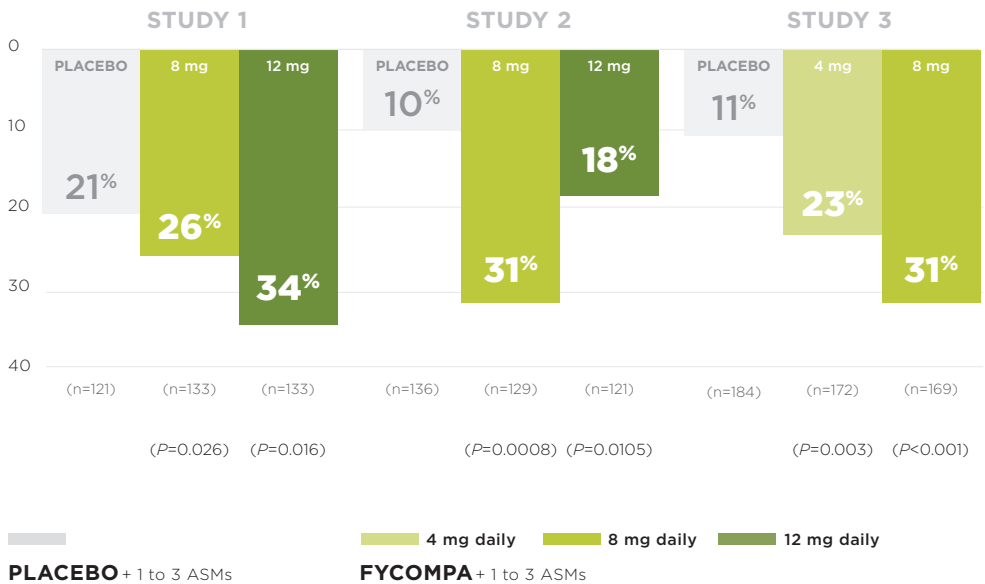
Demonstrated Efficacy

In Partial-Onset Seizures, With or Without Secondary Generalization[1]

A **statistically significant decrease in all partial-onset seizures** was observed at doses of 4 mg to 12 mg per day[1]

PRIMARY ENDPOINT:

MEDIAN % REDUCTION IN SEIZURE FREQUENCY PER 28 DAYS



PLACEBO + 1 to 3 ASMs

FYCOMPA + 1 to 3 ASMs

PIVOTAL PHASE 3 STUDIES

Results for 3 randomized, double-blind, placebo-controlled, multicenter studies on the effectiveness of FYCOMPA as adjunctive therapy in patients 12 years of age and older with partial-onset seizures.[1]

- The total treatment period was 19 weeks (6: titration; 13: maintenance)[1]
- Patients had more than 5 partial-onset seizures during the 6-week baseline period[1]

SELECTED SAFETY INFORMATION

DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS)

DRESS, also known as **multiorgan hypersensitivity**, has been reported in patients taking AEDs, including FYCOMPA. DRESS may be fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling, in association with other organ system involvement. If signs or symptoms are present, immediately evaluate the patient and discontinue FYCOMPA if an alternative etiology for signs or symptoms cannot be established.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

Demonstrated Efficacy

In Partial-Onset Seizures, With or Without Secondary Generalization[1]

MEDIAN % REDUCTION IN SEIZURE FREQUENCY WITH NONINDUCER AND INDUCER ASMs[1,12,*,†]

	NONINDUCER ASMs		INDUCER ASMs	
	Placebo +1 to 3 ASMs	FYCOMPA® +1 to 3 ASMs	Placebo +1 to 3 ASMs	FYCOMPA® +1 to 3 ASMs
2 mg daily	16% (n=72)	23% (n=70)	14% (n=94)	16% (n=90)
4 mg daily	16% (n=72)	22% (n=69)	14% (n=94)	33% (n=84)
8 mg daily	19% (n=152)	45% (n=117)	12% (n=196)	24% (n=170)
12 mg daily	19% (n=80)	54% (n=35)	9% (n=102)	22% (n=79)

*Patients from Latin American regions are excluded because of a significant treatment-by-region interaction due to high placebo response.

†Concomitant enzyme-inducing ASMs (eg, carbamazepine, oxcarbazepine, or phenytoin) resulted in a substantial reduction in efficacy.

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Demonstrated Efficacy

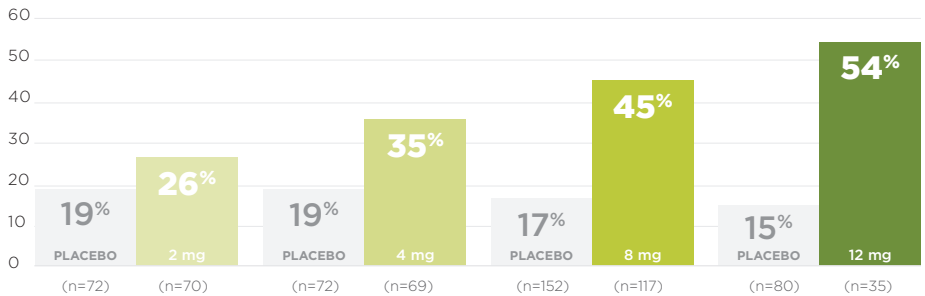
In Partial-Onset Seizures, With or Without Secondary Generalization[1]

Up to 54% of patients experienced a **≥50% REDUCTION** in seizure frequency[1]

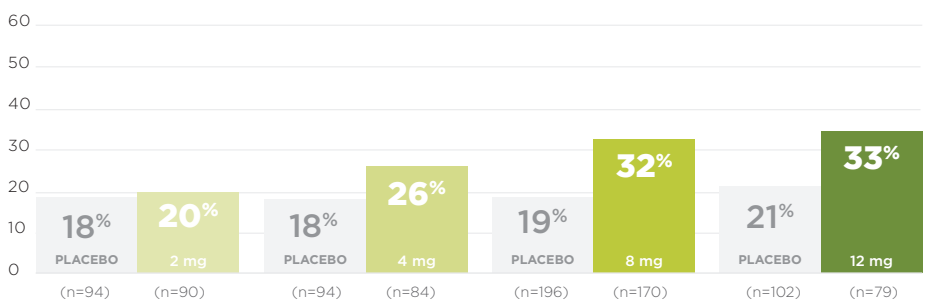
SECONDARY ENDPOINT:

PERCENTAGE OF PATIENTS WHO EXPERIENCED ≥ 50% REDUCTION IN SEIZURE FREQUENCY

RESPONDER RATE NONINDUCER ASMs*†



RESPONDER RATE INDUCER ASMs*†



PLACEBO + 1 to 3 ASMs

FYCOMPA + 1 to 3 ASMs
- 4 mg daily
- 8 mg daily
- 12 mg daily

Responder rate is defined as the percentage of patients experiencing a 50% or greater reduction in partial-onset seizure frequency.

*Patients from Latin American regions are excluded because of a significant treatment-by-region interaction due to high placebo response.

†Concomitant enzyme-inducing ASMs (eg, carbamazepine, oxcarbazepine, or phenytoin) resulted in a substantial reduction in efficacy.

SELECTED SAFETY INFORMATION

DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS)

DRESS, also known as **multiorgan hypersensitivity**, has been reported in patients taking AEDs, including FYCOMPA. DRESS may be fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling, in association with other organ system involvement. If signs or symptoms are present, immediately evaluate the patient and discontinue FYCOMPA if an alternative etiology for signs or symptoms cannot be established.

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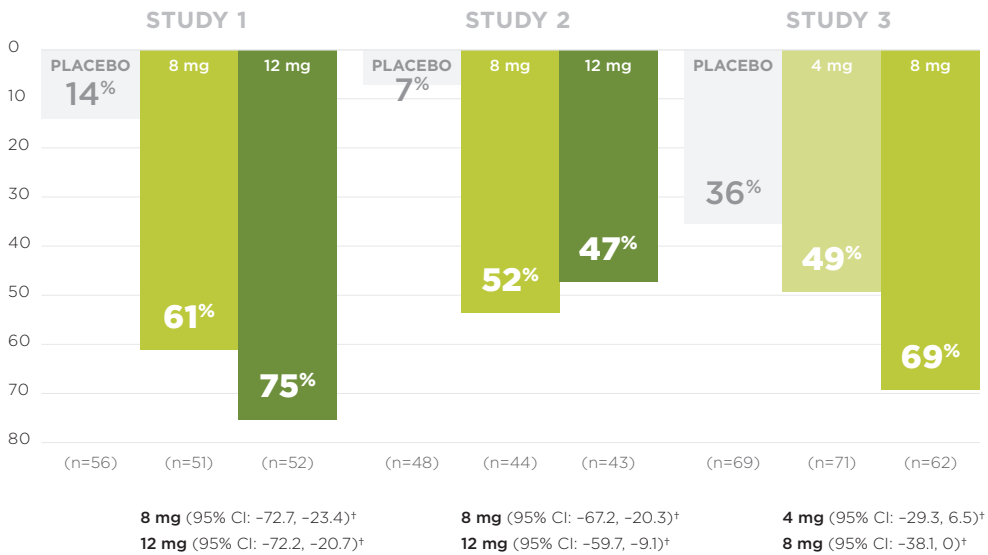
Secondarily Generalized

Convulsive Seizure Frequency Reduction[12]

SUBGROUP ANALYSIS:

MEDIAN % REDUCTION IN SEIZURE FREQUENCY PER 28 DAYS*



Studies 1 and 2 evaluated FYCOMPA 8 mg and 12 mg vs placebo; Study 3 evaluated FYCOMPA 2 mg, 4 mg, and 8 mg vs placebo[1]

LIMITATIONS

Prespecified exploratory endpoint not adjusted for multiplicity and not adequately powered to show statistical significance.

*Analysis included patients who experienced this seizure type during the baseline period.
†Confidence intervals reflect lower and upper limit of the median difference to placebo.

SELECTED SAFETY INFORMATION

DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS)

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Secondarily Generalized Convulsive Seizure Freedom

SEIZURE FREEDOM RATES IN SECONDARILY GENERALIZED CONVULSIVE SEIZURES[12]

MORE THAN **1 in 3** **PATIENTS** (36%)

with **secondarily generalized seizures** were

CONVULSIVE SEIZURE FREE[1,*,†]

during the 13-week maintenance phase

POST-HOC EXPLORATORY ENDPOINT

	PLACEBO (n=442)	FYCOMPA 4 mg daily (n=431)	FYCOMPA 8 mg daily (n=431)	FYCOMPA 12 mg daily (n=255)
STUDY 1	10% (n=5)		**33%** (n=15)	**36%** (n=15)
STUDY 2	5% (n=2)		**26%** (n=9)	**16%** (n=5)
STUDY 3	24% (n=15)	**23%** (n=15)	**23%** (n=15)	

LIMITATIONS[1]

Secondarily generalized seizure freedom was a post-hoc analysis not adjusted for multiplicity and not adequately powered to show statistical significance. These analyses for seizure freedom are descriptive.

*Analysis included patients who experienced this seizure type during the baseline period.

†Seizure freedom during maintenance period in patients who completed the Phase 3 study maintenance phase.

SELECTED SAFETY INFORMATION

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Adverse Reactions

In Partial-Onset Seizure Studies

ARs IN ≥5% OF PATIENTS IN THE 8-mg AND 12-mg GROUPS AND ≥1% MORE THAN PLACEBO

	PLACEBO % (n=442)	4 mg % (n=172)	8 mg % (n=431)	12 mg % (n=255)
Dizziness	9	16	32	43
Somnolence	7	9	16	18
Headache	11	11	11	13
Irritability	3	4	7	12
Fatigue	5	8	8	12
Falls	3	2	5	10
Ataxia	0	1	3	8
Nausea	5	3	6	8
Vertigo	1	4	3	5
Back pain	2	2	2	5
Balance disorder	1	0	5	3

- The following ARs were dose-related and occurred mostly during the titration phase: dizziness and disturbance in gait or coordination (including ataxia, gait disturbance, balance disorder, and abnormal coordination), somnolence and fatigue-related events (including fatigue, asthenia, and lethargy).[1]
- For almost every adverse reaction, rates were higher on 12 mg and more often led to dose reduction or discontinuation.[1]

SELECTED SAFETY INFORMATION

WITHDRAWAL OF AEDS

A gradual withdrawal is generally recommended with AEDs to minimize the potential of increased seizure frequency, but if withdrawal is a response to adverse events, prompt withdrawal can be considered.

MOST COMMON ADVERSE REACTIONS

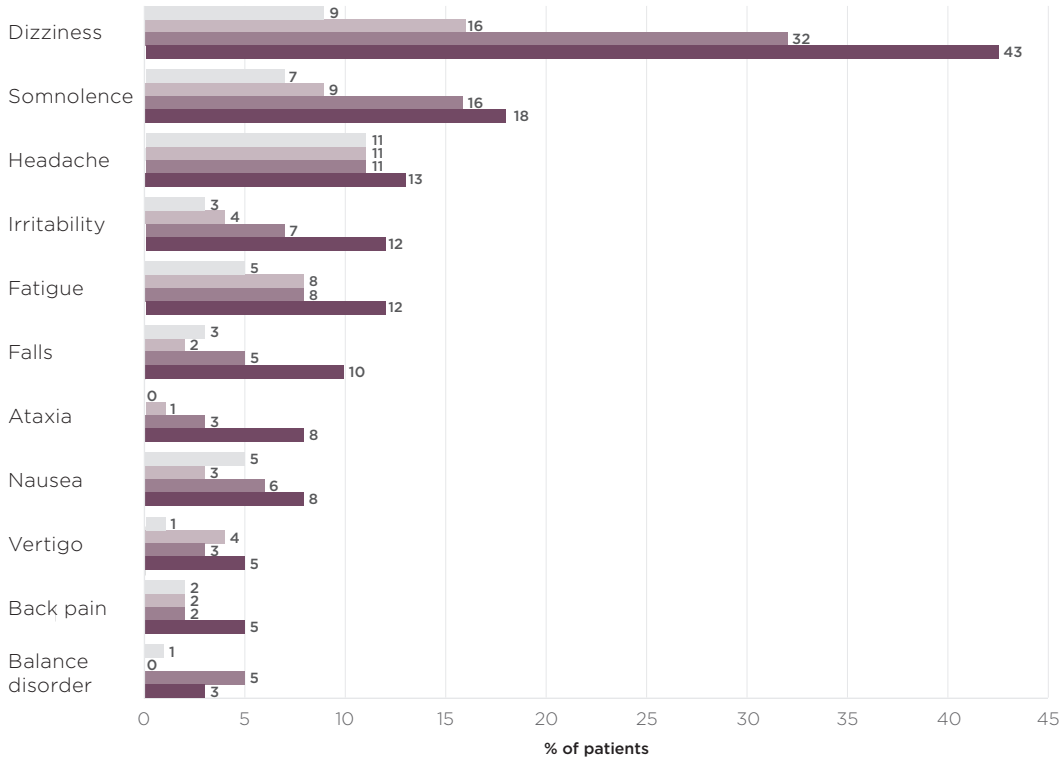
The most common adverse reactions in patients aged 12 years and older receiving FYCOMPA (≥5% and ≥1% higher than placebo) include dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, headache, vomiting, contusion, abdominal pain, and anxiety. Adverse reactions in patients aged 4 to <12 years were generally similar to patients aged 12 years and older.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

Adverse Reactions

In Partial-Onset Seizure Studies

ARs IN ≥5% OF PATIENTS IN THE 8-mg AND 12-mg GROUPS AND ≥1% MORE THAN PLACEBO



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- For almost every adverse reaction, rates were higher on 12 mg and more often led to dose reduction or discontinuation.[1]

SELECTED SAFETY INFORMATION

WITHDRAWAL OF AEDS

A gradual withdrawal is generally recommended with AEDs to minimize the potential of increased seizure frequency, but if withdrawal is a response to adverse events, prompt withdrawal can be considered.

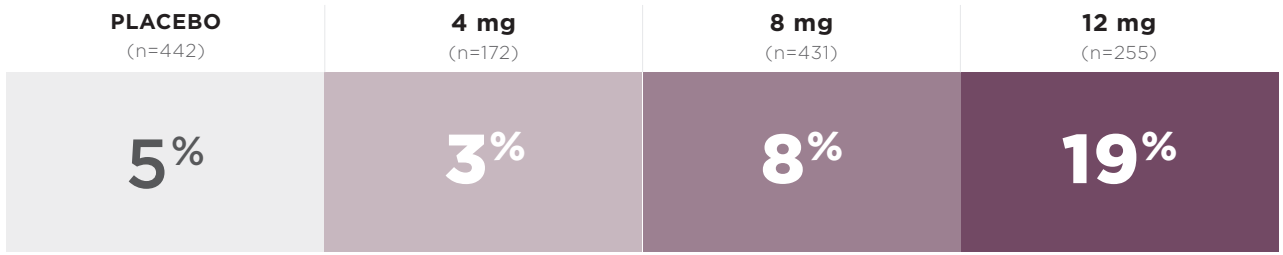
MOST COMMON ADVERSE REACTIONS

The most common adverse reactions in patients aged 12 years and older receiving FYCOMPA (≥5% and ≥1% higher than placebo) include dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, headache, vomiting, contusion, abdominal pain, and anxiety. Adverse reactions in patients aged 4 to <12 years were generally similar to patients aged 12 years and older.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

Discontinuation Rates Rose With FYCOMPA® Dosage

PATIENTS WHO DISCONTINUED DUE TO AN ADVERSE REACTION, BY DOSE[1]



The adverse reactions most commonly leading to discontinuation (≥1% in the 8 mg or 12 mg/day FYCOMPA group and greater than placebo) were dizziness, somnolence, vertigo, aggression, anger, ataxia, blurred vision, irritability, and dysarthria.

Dizziness and disturbance in gait or coordination led to discontinuation in 3% of FYCOMPA-treated patients vs 1% of placebo-treated patients. Somnolence or fatigue-related events led to discontinuation in 2% of FYCOMPA-treated patients and 0.5% of placebo-treated patients. Elderly patients had an increased risk of these adverse reactions compared to younger adults and pediatric patients.[1]

SELECTED SAFETY INFORMATION

WITHDRAWAL OF AEDS

A gradual withdrawal is generally recommended with AEDs to minimize the potential of increased seizure frequency, but if withdrawal is a response to adverse events, prompt withdrawal can be considered.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions in patients aged 12 years and older receiving FYCOMPA (≥5% and ≥1% higher than placebo) include dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, headache, vomiting, contusion, abdominal pain, and anxiety. Adverse reactions in patients aged 4 to <12 years were generally similar to patients aged 12 years and older.

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From Clinical Trials to Clinical Experience

The more FYCOMPA® is used in clinical practice, the more we learn. Post-approval studies in partial-onset seizures include:

- Patients whose first ASM treatment had failed*
- Treatment-naïve patients†

Titration and maintenance doses studied

In The FAME Study (Study 412) of first-adjunctive FYCOMPA:[14]

- A majority took either 4 mg or 6 mg (70/85; 82%)
- More than half of patients took 4 mg (43/85; 51%)

In the FREEDOM Study (Study 342) of FYCOMPA as monotherapy:[12]

- A majority of patients took 4 mg (68/89; 76%)‡
- Patients not controlled at 4 mg were titrated to 8 mg daily (21/73; 29%)§

*The FAME Study (Study 412). Final doses depended on clinical response and tolerability.
†The FREEDOM Study (Study 342)
‡N=89 Treated (ITT)
§N=73 Entered 4 mg Maintenance Period (mITT)

SELECTED SAFETY INFORMATION

DRUG INTERACTIONS

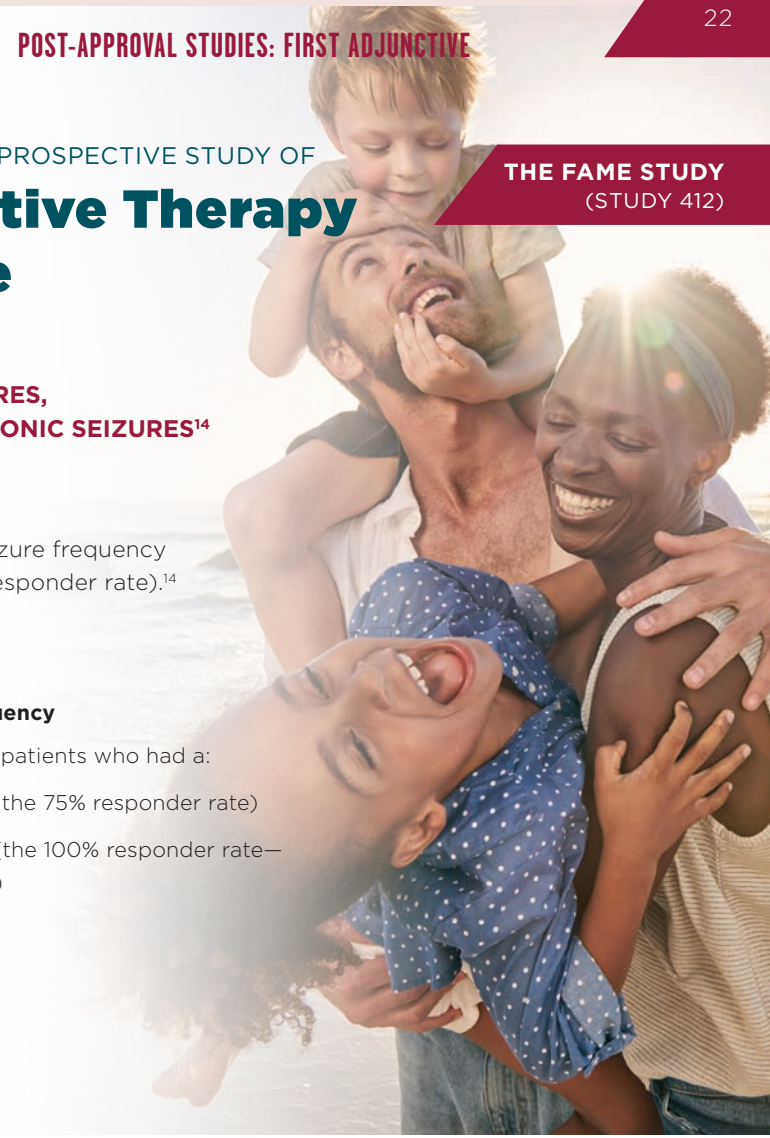
FYCOMPA may decrease the efficacy of contraceptives containing levonorgestrel. Plasma levels of perampanel were decreased when administered with known moderate and strong CYP3A4 inducers, including, carbamazepine, phenytoin, or oxcarbazepine. Multiple dosing of FYCOMPA 12 mg per day enhanced the effects of alcohol on vigilance and alertness, and increased levels of anger, confusion, and depression. These effects may also be seen when FYCOMPA is used in combination with other CNS depressants.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

A 24-WEEK MAINTENANCE, MULTICENTER, OPEN-LABEL, PROSPECTIVE STUDY OF

FYCOMPA® as First Adjunctive Therapy After Monotherapy Failure

THE FAME STUDY
(STUDY 412)



IN PATIENTS AGED ≥12 YEARS WITH PARTIAL-ONSET SEIZURES, WITH OR WITHOUT SECONDARILY GENERALIZED TONIC-CLONIC SEIZURES[14]

PRIMARY ENDPOINT:

The percentage of patients who had a ≥50% reduction in total seizure frequency during the Maintenance Period as compared to baseline (a 50% responder rate).[14]

SECONDARY ENDPOINTS:

Secondarily generalized tonic-clonic seizures: total seizure frequency

The percentage of patients who had a:

- ≥50% reduction (the 50% responder rate)
- ≥75% reduction (the 75% responder rate)
- 100% reduction (the 100% responder rate—convulsive seizure freedom)

Total seizure frequency

The percentage of patients who had a:

- ≥75% reduction (the 75% responder rate)
- 100% reduction (the 100% responder rate—seizure freedom)

SELECTED SAFETY INFORMATION

PREGNANCY AND LACTATION

Physicians are advised to recommend that pregnant patients taking FYCOMPA enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. Caution should be exercised when FYCOMPA is administered to pregnant or nursing women as there are no adequate data on the developmental risk associated with use in pregnant women, and no data on the presence of perampanel in human milk, the effects on the breastfed child, or the effects of the drug on milk production.

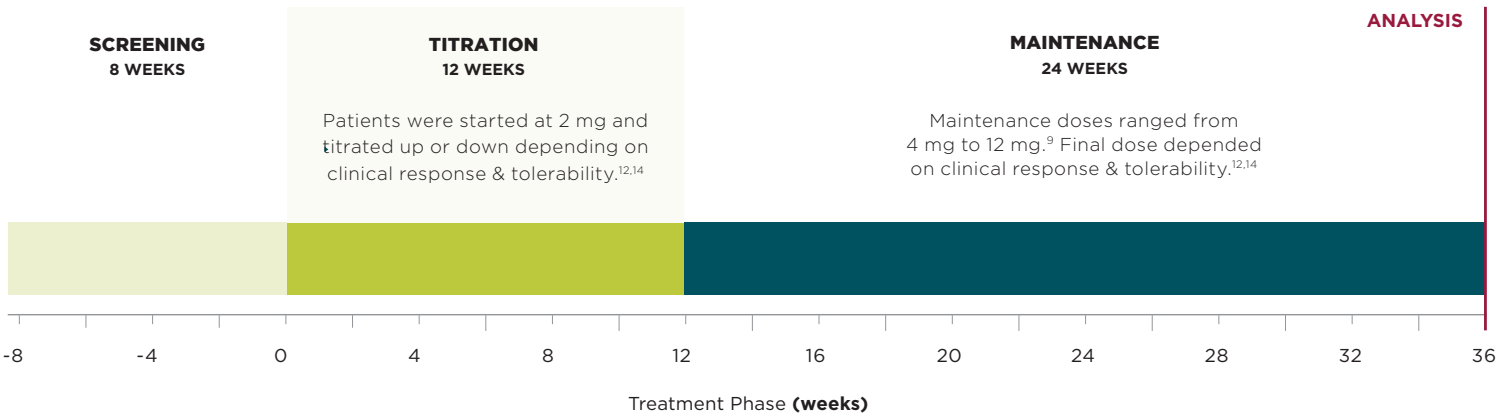
Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

FYCOMPA® as First Adjunctive Therapy After Monotherapy Failure

THE FAME STUDY
(STUDY 412)

STUDY DESIGN[14]

During the Titration Period of this phase 4 study, patients received FYCOMPA® 2 mg once daily at bedtime. Daily dose was increased incrementally at ≥2-week intervals, by 2 mg, depending on clinical response and tolerability.[14]



- Patients had ≥2 partial-onset seizures at intervals of ≥24 hours during the 8 weeks prior to Week 0[12]
- Patients had been taking ASM monotherapy administered at a stable dose for 8 weeks prior to Week 0[12]
- Treatment-emergent adverse events (TEAEs), withdrawal from treatment, and clinical laboratory evaluations (haematology, clinical chemistry, and urinalysis) were assessed[14]

SELECTED SAFETY INFORMATION

PREGNANCY AND LACTATION

Physicians are advised to recommend that pregnant patients taking FYCOMPA enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. Caution should be exercised when FYCOMPA is administered to pregnant or nursing women as there are no adequate data on the developmental risk associated with use in pregnant women, and no data on the presence of perampanel in human milk, the effects on the breastfed child, or the effects of the drug on milk production.

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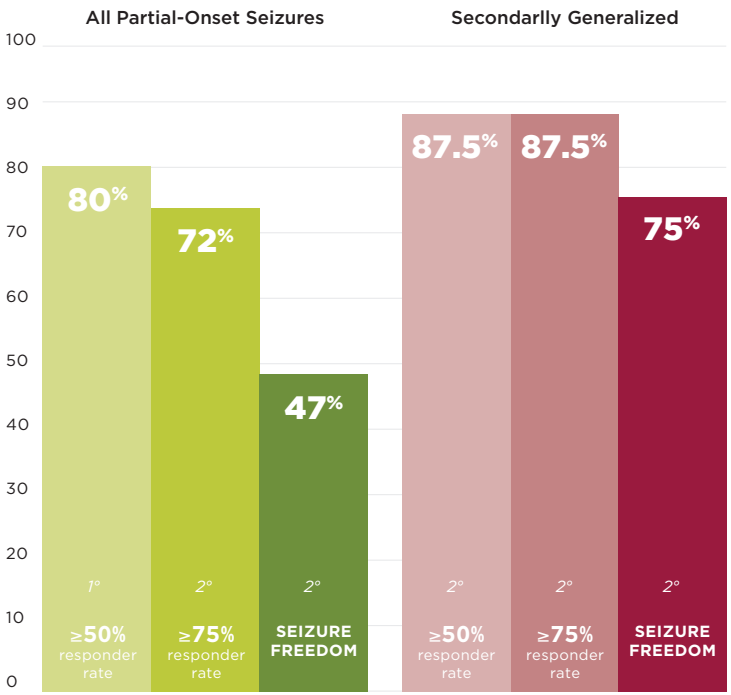
FYCOMPA® as First Adjunctive Therapy After Monotherapy Failure

THE FAME STUDY
(STUDY 412)

OVERALL RESPONSE RATES AT 24 WEEKS[14]

PERCENTAGE OF PATIENTS WITH REDUCED SEIZURE FREQUENCIES



1° = primary endpoint; 2° = secondary endpoints

PATIENTS (n/N) WITH REDUCTION IN SEIZURE FREQUENCIES

	All Partial-Onset Seizures	Secondarily Generalized
≥50% reduction	68/85	14/16
≥75% reduction	61/85	14/16
100% reduction	40/85	12/16

LIMITATIONS[14]

- The study was open-label and did not include a control arm
- Appropriate multiplicity adjustments were not applied
- This information is descriptive
- The study included a relatively small number of patients

SELECTED SAFETY INFORMATION

PREGNANCY AND LACTATION

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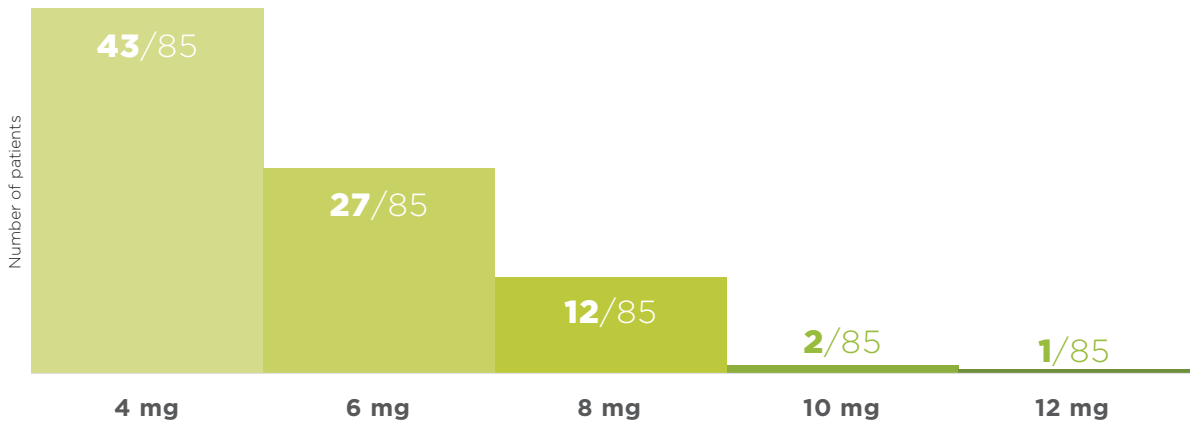
FYCOMPA® as First Adjunctive Therapy After Monotherapy Failure

THE FAME STUDY (STUDY 412)

FINAL MAINTENANCE DOSES[12,*]

Final dose depended on clinical response and tolerability.[14,†]



*Includes 37 patients taking moderate and strong CYP3A4 inducers, which can cause a reduction in FYCOMPA® plasma levels and may require higher doses of FYCOMPA. The study was not designed to evaluate the effect of concomitant enzyme inducer/non-inducer ASMs.[1,12]

†According to the investigator's judgment.[12]

SELECTED SAFETY INFORMATION

PREGNANCY AND LACTATION

Physicians are advised to recommend that pregnant patients taking FYCOMPA enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. Caution should be exercised when FYCOMPA is administered to pregnant or nursing women as there are no adequate data on the developmental risk associated with use in pregnant women, and no data on the presence of perampanel in human milk, the effects on the breastfed child, or the effects of the drug on milk production.

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FYCOMPA® as First Adjunctive Therapy After Monotherapy Failure

THE FAME STUDY (STUDY 412)

ADVERSE EVENTS AT 24 WEEKS

Most common TEAEs[14]	(n=102)
Dizziness	**50.0%**
Somnolence	**9.8%**
Headache	**8.8%**

Discontinuations[12]	24.5% (n=26/106)
Adverse event*	**13.2%** (n=14)
Withdrawal of consent	**3.8%** (n=4)
Major protocol violation	**2.8%** (n=3)
Lost to follow-up	**1.9%** (n=2)
Other	**2.8%** (n=3)

Number of patients included in the analyses:[12]

- Enrolled subjects: N=106 (3 did not receive drug, 1 lost to follow-up)
- Safety set: N=102 (96.23%)
- Full analysis set: N=85 (80.19%)

*The adverse events most commonly leading to discontinuation (≥1% of patients) were dizziness, headache, and seizure.[12]

SELECTED SAFETY INFORMATION

PREGNANCY AND LACTATION

Physicians are advised to recommend that pregnant patients taking FYCOMPA enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. Caution should be exercised when FYCOMPA is administered to pregnant or nursing women as there are no adequate data on the developmental risk associated with use in pregnant women, and no data on the presence of perampanel in human milk, the effects on the breastfed child, or the effects of the drug on milk production.

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A 26-WEEK MAINTENANCE, OPEN-LABEL STUDY OF NEWLY DIAGNOSED OR UNTREATED PATIENTS WITH PARTIAL-ONSET SEIZURES[12]

THE FREEDOM STUDY
(STUDY 342)

FYCOMPA® as Monotherapy

A MULTICENTER, UNCONTROLLED, OPEN-LABEL STUDY IN PATIENTS AGED ≥12 YEARS

91
Patients entered study

89
Patients were treated (ITT)

73
Patients entered 4 mg Maintenance period (mITT)

All patients presented with at least 1 of the following seizure types:

- Simple partial seizures with or without motor signs (16%)
- Complex partial seizures (61%)
- Complex partial seizures with secondary generalization (64%)

The median baseline seizure frequency was 2 seizures per 12 weeks.

ITT=intent-to-treat; mITT=modified intent-to-treat

SELECTED SAFETY INFORMATION

HEPATIC AND RENAL IMPAIRMENT

Use in patients with severe hepatic or severe renal impairment is not recommended. Dosage adjustments are recommended in patients with mild or moderate hepatic impairment. Use with caution in patients with moderate renal impairment.

DRUG ABUSE AND DEPENDENCE

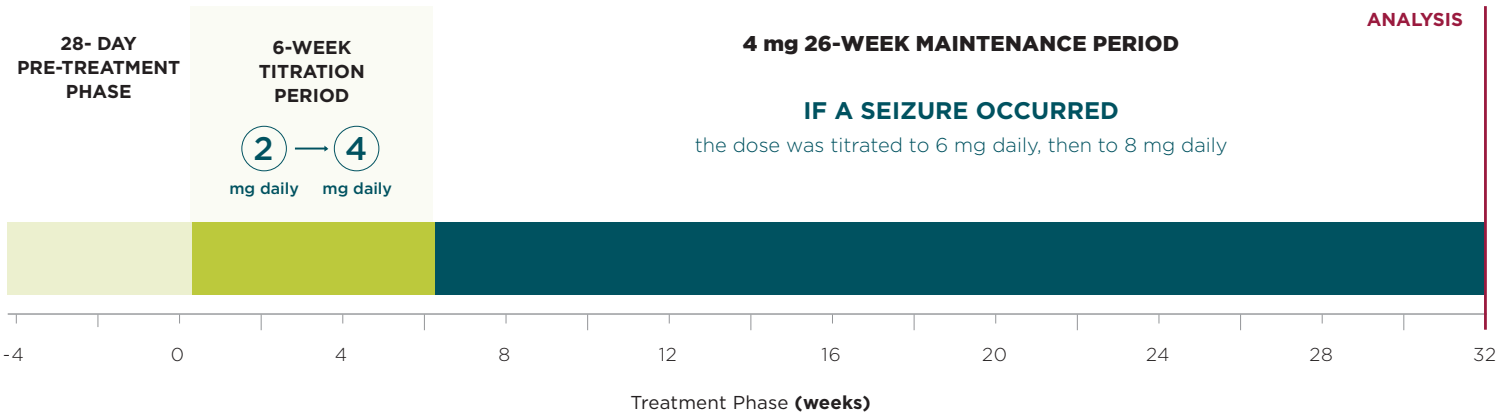
FYCOMPA is a Schedule III controlled substance and has the potential to be abused and lead to drug dependence and withdrawal symptoms including anxiety, nervousness, irritability, fatigue, asthenia, mood swings, and insomnia.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

FYCOMPA® as Monotherapy

THE FREEDOM STUDY
(STUDY 342)

STUDY DESIGN[12]



STUDY OBJECTIVE

To evaluate the seizure-free rate during a 26-week Maintenance Period. The evaluation criteria focused on the efficacy and safety of FYCOMPA® when used as monotherapy in patients with new-onset partial-onset seizures, including secondarily generalized seizures.[12]
The initial approval of FYCOMPA for partial-onset seizures, with or without secondary generalization, was based on 3 trials in patients not controlled with 1 to 3 concomitant anti-seizure medications.[1] These patients had a mean duration of epilepsy of ~21 years and a median baseline seizure frequency of 9 to 14 seizures per 28 days.[1] Based on an extrapolation of the data from these 3 trials, the indication of FYCOMPA was expanded to include monotherapy use for partial-onset seizures.[12]

- 96% (70/73) of patients were newly diagnosed (mITT)
- The modified intent-to-treat (mITT) analysis set (n=73) was a subset of the intent-to-treat (ITT) analysis set (N=89) that entered the 4 mg Maintenance Period and subsequently had at least 1 post-dose primary efficacy measurement
- A Japanese and South Korean study

SELECTED SAFETY INFORMATION

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THE FREEDOM STUDY
(STUDY 342)

THE MAJORITY OF NEWLY DIAGNOSED OR UNTREATED PATIENTS WITH PARTIAL-ONSET SEIZURES WERE

Convulsive Seizure Free at 4 mg

After 26 Weeks of Monotherapy[1,2]

4 mg SEIZURE-FREE RATES AT 26 WEEKS[2]

CONVULSIVE SEIZURE FREE AT 4 mg

65%
OF PATIENTS
(n=31/48)

Partial-Onset Seizures with Secondary Generalization*

SEIZURE FREE AT 4 mg

63%
OF PATIENTS
(n=46/73)

Partial-Onset Seizures

21 out of 73 patients were not controlled at 4 mg and were titrated to 8 mg/day.

LIMITATIONS

The study was open-label and did not include a control arm. Appropriate multiplicity adjustments were not applied. This information is descriptive.

*Among the 73 patients with partial-onset seizures who entered the 26-week 4 mg Maintenance Period of the Treatment Phase, 48 had secondarily generalized seizures at baseline.

SELECTED SAFETY INFORMATION

HEPATIC AND RENAL IMPAIRMENT

Use in patients with severe hepatic or severe renal impairment is not recommended. Dosage adjustments are recommended in patients with mild or moderate hepatic impairment. Use with caution in patients with moderate renal impairment.

DRUG ABUSE AND DEPENDENCE

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FYCOMPA® as Monotherapy: Adverse Events at 26 Weeks

THE FREEDOM STUDY (STUDY 342)

During Treatment Phase by 4 mg Final Dose (n=68)[12,*]

ADVERSE EVENTS THAT OCCURRED IN ≥5% OF PATIENTS TAKING FYCOMPA® 4 mg

TREATMENT-EMERGENT ADVERSE EVENTS (TEAEs) (≥5%)	FYCOMPA 4 mg daily† (n=68), n(%)
Dizziness	**18** (26.5%)
Somnolence	**9** (13.2%)
Nasopharyngitis	**9** (13.2%)
Headache	**7** (10.3%)

*Includes patients who completed or discontinued from the 4 mg Treatment Phase.
†Patients with a final dose of 2 mg were grouped into 4 mg.

22 PATIENTS (24.7%) DISCONTINUED TREATMENT DURING THE 4 mg TREATMENT PHASE

- Reasons: adverse event (n=8; 9%), subject choice (n=1; 1.1%), inadequate therapeutic effect (n=3; 3.4%), lost to follow-up (n=2; 2.2%), withdrawal of consent (n=5; 5.6%) and other (n=3; 3.4%)

PSYCHIATRIC DISORDERS AT 4 mg/DAY* (N=68)

- Irritability (n=2; 2.9%), affect lability (n=1; 1.5%), depression (n=1; 1.5%), and insomnia (n=1; 1.5%)

SELECTED SAFETY INFORMATION

HEPATIC AND RENAL IMPAIRMENT

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PRIMARY GENERALIZED TONIC-CLONIC (PGTC) INDICATION APPROVAL

Pivotal Trial for PGTC Seizures Was Conducted With Refractory Patients

PATIENTS HAD ≥3 PRIMARY GENERALIZED TONIC-CLONIC SEIZURES OVER 8 WEEKS AT BASELINE, DESPITE TAKING 1 TO 3 OTHER ASMs.[1,*]

FYCOMPA received approval as adjunctive therapy in patients 12 years of age and older based on a multicenter, randomized, double-blind, placebo-controlled clinical trial.[1,*]

During the 4-week titration period:

- Patients were titrated up to a dose of 8 mg daily or the highest tolerated dose
- Patients entered the maintenance period at the last dose achieved during titration

During the 13-week maintenance period:

- Although dose adjustment is not recommended, depending upon the investigator's clinical judgment, patients with inadequate seizure control could have their dose increased by one 2-mg increment up to a maximum daily dose of 8 mg
- Patients who experienced intolerable adverse events (AEs) could have their dose decreased by one 2-mg increment

*6 most commonly used concomitant ASMs at baseline: valproic acid/ergenyl chrono, lamotrigine, levetiracetam, topiramate, and zonisamide

SELECTED SAFETY INFORMATION

SERIOUS PSYCHIATRIC AND BEHAVIORAL REACTIONS

In the partial-onset seizures clinical trials, hostility- and aggression-related adverse reactions occurred in 12% and 20% of patients randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 6% of patients in the placebo group. These effects were dose-related and generally appeared within the first 6 weeks of treatment, although new events continued to be observed through more than 37 weeks. These effects in FYCOMPA-treated patients led to dose reduction, interruption, and discontinuation more frequently than placebo-treated patients. Homicidal ideation and/or threat have also been reported postmarketing in patients treated with FYCOMPA. The combination of alcohol and FYCOMPA significantly worsened mood and increased anger. Patients taking FYCOMPA should avoid the use of alcohol. Patients, their caregivers, and families should be informed that FYCOMPA may increase the risk of psychiatric events. Patients should be monitored during treatment and for at least one month after the last dose of FYCOMPA, and especially when taking higher doses and during the initial few weeks of drug therapy (titration period) or at other times of dose increases. Similar serious psychiatric and behavioral events were observed in the primary generalized tonic-clonic (PGTC) seizure clinical trial.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

INTRODUCTION

PARTIAL-ONSET SEIZURES

PGTC SEIZURES

Primary Generalized Tonic-Clonic (PGTC) Seizures

PRIMARY ENDPOINT

76% **MEDIAN REDUCTION** in PGTC seizure frequency per 28 days (n=81) vs a 38% reduction with placebo (n=81) (*P*<0.0001)[1,3]

SECONDARY ENDPOINT: RESPONDER RATE

64% (n=52) of patients taking FYCOMPA® (perampanel) during the maintenance phase exhibited a **50% TO 100% REDUCTION** in PGTC seizure frequency vs placebo (40%; n=32) (*P*=0.0019)[12]

NEARLY **1 in 3** **PATIENTS** (31%)

In a prespecified exploratory endpoint.

with **PGTC seizures** taking FYCOMPA during the 13-week maintenance phase (n=25) were

CONVULSIVE SEIZURE FREE

vs placebo (12%; n=10)[3,12]

PROPORTION OF PATIENTS EXHIBITING PGTC SEIZURE FREQUENCY REDUCTIONS

	REDUCTION				INCREASE
	75% TO 100%	50% TO <75%	25% TO <50%	0 TO <25%	
FYCOMPA + 1 to 3 ASMs	**48%** (n=39)	**16%** (n=13)	**15%** (n=12)	**11%** (n=9)	**10%** (n=8)
PLACEBO + 1 to 3 ASMs	24% (n=19)	16% (n=13)	20% (n=16)	12% (n=10)	28% (n=23)

LIMITATION

No adjustment was made for multiple comparisons.

SELECTED SAFETY INFORMATION

SUICIDAL BEHAVIOR AND IDEATION

Antiepileptic drugs (AEDs), including FYCOMPA, increase the risk of suicidal thoughts or behavior in patients. Anyone considering prescribing FYCOMPA or any other AED must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Patients, their caregivers, and families should be informed of the risk and advised to monitor and immediately report the emergence or worsening of depression, suicidal thoughts or behavior, thoughts about self-harm and/or any unusual changes in mood or behavior. Should suicidal thoughts and behavior emerge during treatment, consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

INTRODUCTION

PARTIAL-ONSET SEIZURES

PGTC SEIZURES

Primary Generalized Tonic-Clonic (PGTC) Seizures

MOST FREQUENTLY (≥4%) REPORTED ADVERSE REACTIONS[1]

	PLACEBO % (n=82)	FYCOMPA 8 mg % (n=81)
Dizziness	6	**32**
Fatigue	6	**15**
Headache	10	**12**
Somnolence	4	**11**
Irritability	2	**11**
Vertigo	2	**9**
Vomiting	2	**9**
Weight gain	4	**7**

	PLACEBO % (n=82)	FYCOMPA 8 mg % (n=81)
Contusion	4	**6**
Nausea	5	**6**
Abdominal pain	1	**5**
Anxiety	4	**5**
Urinary tract infection	1	**4**
Ligament sprain	0	**4**
Balance disorder	1	**4**
Rash	1	**4**

The rate of discontinuation due to adverse reactions was:

- 11.1% (n=9) in patients taking FYCOMPA®
- 6.1% (n=5) in patients taking placebo.[2,4]

Adverse reactions most commonly leading to discontinuation (≥2% in the FYCOMPA group and greater than placebo) were vomiting and dizziness[1,4]

†ASMs at baseline: valproic acid/ergenyl chrono, lamotrigine, levetiracetam, topiramate, zonisamide, clonazepam, carbamazepine, phenytoin, phenobarbital, clobazam, ethosuximide, oxcarbazepine, lacosamide, gabapentin, lorazepam, acetazolamide, clorazepic acid, mesuximide, sultiame, and tiagabine.

SELECTED SAFETY INFORMATION

DIZZINESS AND GAIT DISTURBANCE

FYCOMPA caused dose-related increases in events related to dizziness and disturbance in gait or coordination. Dizziness and vertigo were reported in 35% and 47% of patients in the partial-onset seizure trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 10% of placebo-treated patients. Gait disturbance related events were reported in 12% and 16% of patients in the partial-onset seizure clinical trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 2% of placebo-treated patients. These adverse reactions occurred mostly during the titration phase. These adverse reactions were also observed in the PGTC seizure clinical trial.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

FYCOMPA® Today

FYCOMPA AND CATALYST: A COMMITMENT TO TREATING EPILEPSY

2012 — Adjunctive treatment for **partial-onset seizures**

2015 — Adjunctive treatment for **PGTC seizures**

2016 — FYCOMPA **Oral Suspension**

2017 — **Monotherapy** for partial-onset seizures

2018 — Partial-onset seizures in **pediatric patients as young as 4** years old

TODAY

Over half a million patients have been prescribed FYCOMPA worldwide[12,*,†]

- Well-studied, with **80+ global studies** published or ongoing[15]
- **9+ years of clinical experience**
- Available in **2 formulations**[1]
- Approved in **72 countries**[12,†]

*Worldwide figure through December 2021. Over 50,000 patients prescribed FYCOMPA in the United States.

†Across different indications.

SELECTED SAFETY INFORMATION

SOMNOLENCE AND FATIGUE

FYCOMPA caused dose-dependent increases in somnolence and fatigue-related events. Somnolence was reported in 16% and 18% of patients in the partial-onset seizure trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 7% of placebo-treated patients. Fatigue-related events were reported in 12% and 15% of patients in the partial-onset seizure trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 5% of placebo-treated patients. These adverse reactions occurred mostly during the titration phase. These adverse reactions were also observed in the PGTC seizure clinical trial. Patients should be advised against engaging in hazardous activities requiring mental alertness, such as operating motor vehicles or dangerous machinery, until the effect of FYCOMPA is known. Patients should be carefully observed for signs of central nervous system (CNS) depression when FYCOMPA is used with other drugs with sedative properties because of potential additive effects.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

CONSIDER **FYCOMPA®** WHEN

Treating Convulsive Seizures

Fycompa™ (perampanel) TABLETS 2•4•6•8•10•12 mg ORAL SUSPENSION 0.5 mg/mL CII

For your patients with:

- **Partial-onset seizures that secondarily generalize**
  Monotherapy or adjunctive therapy or for patients ≥4 years of age
- **Primary generalized tonic-clonic (PGTC) seizures**
  Adjunctive therapy for patients ≥12 years of age

SELECTED SAFETY INFORMATION

FALLS

Falls were reported in 5% and 10% of patients in the partial-onset seizure clinical trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 3% of placebo-treated patients.

Please see additional Important Safety Information throughout and available Prescribing Information, including Boxed WARNING.

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Catalyst pharmaceuticals