Ensure Your Patients Stay on

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

"Dispense as Written" Requirements for All 50 States

To continue to choose FYCOMPA®, you must write the prescription using the enclosed state-specific language, verbatim.

Review this language closely to ensure you've written the prescription exactly as specified.

INDICATION

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.

IMPORTANT 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 Selected Safety Information throughout and accompanying Prescribing Information, including Boxed WARNING.

State-by-State Requirements for Preventing Generic Substitution[1]

Adapted from the 2024 Survey of Pharmacy Law

Alabama	Expressly indicate in some manner.
Alaska	Write in own handwriting, in addition to signature, "Brand Necessary."
Arizona	Expressly indicate that substitution is not allowed.
Arkansas	Write in own handwriting, in addition to signature, "Brand Necessary."
California	Indicate orally or in own handwriting "Do Not Substitute" or similar words. Allows use of preprinted "Do Not Substitute" box, provided prescriber personally initials box.
Colorado	Handwrite "Dispense as Written" or hand-initial preprinted box labeled "Dispense as Written." May also be done electronically.
Connecticut	Handwrite "DAW" or "Dispense as Written," along with "Medically Necessary."
Delaware	Handwrite "DAW" or "Dispense as Written," along with "Brand Necessary" or "Brand Medically Necessary."
District of Columbia	Expressly indicate in some manner.
Florida	Expressly indicate in some manner.
Georgia	Prescriber's signature shall validate prescription and, unless prescriber handwrites "Brand Necessary" or "Brand Medically Necessary," shall designate approval of drug substitution by pharmacist.
Guam	Handwrite "No Substitution" or diminutive "No Sub" on face of prescription.
Hawaii	Indicate "Brand Necessary" or "Brand Medically Necessary" in own handwriting. Refer to Department of Health, Food and Drug Branch.
Idaho	Order by any means that brand-name drug must be dispensed.
Illinois	Indicate "May Not Substitute" by marking a designated box. See Section 225 ILCS 85/25.
Indiana	Sign on appropriate line of two-line prescription .
Iowa	Expressly indicate that substitution is not allowed .
Kansas	Sign on appropriate line of two-line prescription. Expressly indicate substitution is not allowed.
Kentucky	Expressly indicate in some manner. "Brand Medically Necessary" to be handwritten on face of prescription by prescriber for Medicaid patients. May indicate on prescription "Do Not Substitute" in own manner, except that indication shall not be preprinted.
Louisiana	Box must be checked to prevent substitution.
Maine	Expressly indicate in some manner. Box must be checked to prevent substitution.
Maryland	"Brand Medically Necessary" to be handwritten on face of prescription by prescriber for Medicaid patients. Expressly indicate that substitution is not allowed.
Massachusetts	Indicate "No Substitution."
Michigan	Handwrite "DAW" or "Dispense as Written." Expressly indicate that prescription is to be dispensed as communicated for prescriptions other than those written.
Minnesota	Handwrite "DAW" or "Dispense as Written," unless prescription is transmitted electronically in accordance with the Code of Federal Regulations, Title 42, Section 423.
Mississippi	Sign on appropriate line of two-line prescription.
Missouri	Order by any means that brand-name drug must be dispensed.
Montana	"Brand Name Medically Necessary" shall be handwritten (or printed if electronically generated) on face of prescription if medically necessary that an equivalent drug product not be selected.
Nebraska	Expressly indicate in some manner.
Nevada	Write in own handwriting "Dispense as Written."
New Hampshire	Handwrite "Medically Necessary" on each paper prescription, use electronic indications when transmitted electronically, or give instructions when transmitted orally that brand-name drug product is medically necessary.

Disclaimer: This information is subject to change and should be confirmed by the prescriber.

ILCS, Illinois Compiled Statutes.

Table adapted with permission from: National Association of Boards of Pharmacy. *Survey of Pharmacy Law.* 2024.

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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State-by-State Requirements for Preventing Generic Substitution[1] (cont'd)

New Jersey	Sign on appropriate line of two-line prescription.
New Mexico	Handwrite "No Substitution" or diminutive "No Sub" on face of prescription.
New York	Indicate "Dispense as Written" in designated box or positively indicate brand for electronic prescriptions. "Brand Medically Necessary" to be handwritten on face of prescription by prescriber for Medicaid patients. Alternative provision requires positive indication for electronic prescriptions.
North Carolina	Sign on appropriate line of two-line prescription. Expressly indicate in some manner.
North Dakota	Write in own handwriting, in addition to signature, "Brand Medically Necessary."
Ohio	Handwrites or actively causes to display on prescription "Dispense as Written," "DAW," "Do Not Substitute," "Brand Medically Necessary," or any other statement or numerical code indicating prescriber's intent to prevent substitution in the case of a written or electronic prescription, including a computer-generated prescription. Such designation shall not be preprinted or stamped on prescription, but a reminder to prescriber of designation procedure may be preprinted or displayed on prescription form or electronic system prescriber uses to issue prescription.[2]
Oklahoma	It is unlawful for a pharmacist to substitute without authority of prescriber or purchaser.
Oregon	Specify in writing, by telephonic communication, or electronic transmission, that there may be no substitution for specified brand name drug in a prescription.[3] Refer to ORS 689.515 and OAR-855-041-1105.
Pennsylvania	Sign prescription to validate and, unless prescriber handwrites "Brand Necessary" or "Brand Medically Necessary," shall designate approval of drug substitution by pharmacist.
Puerto Rico	Write in own handwriting on face of prescription: "Do not interchange."
Rhode Island	Sign prescription to validate and, unless prescriber indicates "Brand Necessary" or "Brand Medically Necessary," shall designate approval of drug substitution by pharmacist. Patient may request, in writing, that brand name be dispensed.
South Carolina	Sign on appropriate line of two-line prescription.
South Dakota	Write in own handwriting, in addition to signature, "Brand Necessary."
Tennessee	Write in own handwriting the following language (but not limited to): (1) "Brand Name Medically Necessary," "Dispense as Written," "Medically Necessary," "Brand Name," "No Generic"; or (2) any abbreviation of the language in section above; or (3) any other prescriber handwritten notation, such as circling preprinted "Dispense as Written" on prescription order, that clearly conveys intent that brand name is necessary for patient.
Texas	Must indicate "Brand Necessary" or "Brand Medically Necessary" in own handwriting.
Utah	Expressly indicate in some manner. Allows use of preprinted "Do Not Substitute" checkbox.
Vermont	Write "Brand Necessary," "No Substitution," "Dispense as Written," or "DAW" in own handwriting. See 18 VSA §4606 Brand Certification.
Virginia	"Brand Medically Necessary" to be handwritten on face of prescription by prescriber for Medicaid patients. For all non-Medicaid patients, phrase must be included but not required to be handwritten.
Washington	Sign on appropriate line of two-line prescription.
West Virginia	Expressly indicate in some manner. Prescriber must write in own handwriting "Brand Medically Necessary."
Wisconsin	Expressly indicate in some manner.
Wyoming	Expressly indicate that substitution is not allowed.

Disclaimer: This information is subject to change and should be confirmed by the prescriber.

Important: Note that previous instructions to not substitute may not apply to a new prescription. When prescribing via Electronic Medical Record system, select branded "FYCOMPA" from the medication list.

ORS, Oregon Revised Statutes; VSA, Vermont Statutes Annotated.

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.

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.

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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.

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.

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.

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.

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.

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.

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.

References: 1. National Association of Boards of Pharmacy. *Survey of Pharmacy Law.* 2024. **2.** Ohio Laws & Administrative Rules. Section 4729.38. Selecting generically equivalent drugs or interchangeable biological products. https://codes.ohio.gov/ohio-revised-code/section-4729.38. **3.** Oregon Board of Pharmacy Laws & Rules. Section 689.515. Regulation of generic drugs. https://oregon.public.law/statutes/ors_689.515.

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Catalyst pharmaceuticals