Fycompa™ (perampanel) tablets CIII
2mg • 4mg • 6mg • 8mg • 10mg • 12mg

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# Product Fact Sheet

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| **ABOUT FYCOMPA®** | FYCOMPA® (perampanel) CIII is now approved for adjunctive therapy in the treatment of primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy age 12 and older.<br><br>PGTC seizures are one of the most common and severe forms of generalized epilepsy, with a high incidence of morbidity and mortality. FYCOMPA was initially approved as adjunctive treatment for partial-onset seizures, with or without secondarily generalized seizures, in patients with epilepsy age 12 and older, in October 2012.<br><br>The FYCOMPA label includes a boxed warning to alert prescribers and patients about the risk of serious and life-threatening neuropsychiatric events. |
| **MECHANISM OF ACTION** | Discovered and developed by Eisai, FYCOMPA is the first and only AMPA (alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) receptor antagonist that targets glutamate activity at postsynaptic neurons. |
| **FYCOMPA EFFICACY AND SAFETY** | The approval of the new indication was based on a Phase 3, randomized, double-blind, placebo-controlled clinical trial (Study 332) of 162 patients, taking one to three antiepileptic drugs, evaluating the efficacy and safety of FYCOMPA as adjunctive therapy for PGTC seizures in patients with epilepsy age 12 and older.<br><br>The study showed the following results:<br><br>• The study demonstrated that patients treated with FYCOMPA (n=81) achieved a 76% median reduction in PGTC seizure frequency, which was statistically significant compared to 38% with placebo (n=81).<br>• Additionally, 64% of patients treated with FYCOMPA experienced a 50% or greater reduction in PGTC seizure frequency vs. 40% with placebo, which was also statistically significant.<br>• The most frequently reported adverse events (≥10% in the FYCOMPA group and greater than placebo) in patients treated with FYCOMPA in the Phase 3 clinical trial were dizziness, |

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| | fatigue, headache, somnolence and irritability. The adverse event profile was similar to that noted in the controlled Phase 3 partial-onset seizure trials. |
| **AVAILABLE STRENGTHS** | FYCOMPA is supplied as 2 mg (orange), 4 mg (red), 6 mg (pink), 8 mg (purple), 10 mg (green) and 12 mg (blue) film-coated tablets.<br>  |
| **MORE INFORMATION** | For additional product information, please call Eisai Medical Information at 1-888-274-2378 or visit www.Fycompa.com. |
| **MANUFACTURING AND MARKETING** | FYCOMPA, approved in over 40 countries and currently available in 22 countries, was discovered and developed by Eisai. FYCOMPA is manufactured and marketed in the U.S. by Eisai Inc. |
| **FYCOMPA ASSISTANCE PROGRAM** | To assist patients with access to their medication, Eisai offers patients a FYCOMPA Savings Card.* Patients can register now at Fycompa.com to activate their savings card, if their doctor has already given them one, or download a card and print it at home.<br>*Restrictions apply. Not available to patients enrolled in federal or state healthcare programs, including Medicare, Medicaid, Medigap, VA, DoD or TRICARE.<br>Please refer to complete Eligibility Criteria. |
| **INDICATIONS** | FYCOMPA (perampanel) is indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures and primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older. |

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**

**Serious Psychiatric and Behavioral Reactions**

In the partial- onset clinical trials, hostility- and aggression-related adverse reactions occurred in 12% and 20% of clinical trial patients randomized to receive FYCOMPA at doses of 8 mg and 12 mg/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. The combination of alcohol and FYCOMPA significantly worsened mood and increased anger. Homicidal ideation and/or threat have also been reported postmarketing in patients treated with FYCOMPA. 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 seizure clinical trial.

**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 or 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 seizures clinical trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg/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 seizures clinical trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg/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 primary generalized tonic-clonic seizure clinical trial.

IMPORTANT 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 seizures trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg/day, respectively, compared to 7% of placebo patients. Fatigue-related events were reported in 12% and 15% of patients in the partial-onset seizures trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg/day, respectively, compared to 5% of placebo patients. These adverse reactions occurred mostly during the titration phase. These adverse reactions were also observed in the primary generalized tonic-clonic 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.

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

**Withdrawal of AEDs**
A gradual withdrawal is generally recommended with antiepileptic drugs 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 (≥5% and ≥1% higher than placebo) include dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, headache, vomiting, contusion, abdominal pain, and anxiety.

**Drug Interactions**
FYCOMPA may decrease the efficacy of contraceptives containing levonorgestrel. Plasma levels of FYCOMPA were decreased when administered with carbamazepine, phenytoin, or oxcarbazepine. Concomitant use with strong CYP3A inducers such as St. John's wort or rifampin should be avoided. Multiple dosing of FYCOMPA 12 mg/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 Category C and Lactation**
FYCOMPA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. 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 a nursing woman.

**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 drug substance and has the potential to be abused or lead to drug dependence.

Please see Full Prescribing Information.