

MEDICATION GUIDE
FYCOMPA™ (fī-COM-puh)
(perampanel)
Tablets

Read this Medication Guide before you start taking FYCOMPA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about FYCOMPA?

1. FYCOMPA may cause mental (psychiatric) problems, including:

- new or worse aggressive behavior (including homicidal behavior), hostility, anger, anxiety, or irritability
- being suspicious or distrustful (believing things that are not true)
- other unusual or extreme changes in behavior or mood

Tell your healthcare provider right away if you have any new or worsening mental problems while taking FYCOMPA.

2. Like other antiepileptic drugs, FYCOMPA may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempt to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.

Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Do not stop FYCOMPA without first talking with a healthcare provider.

Stopping FYCOMPA suddenly can cause serious problems. Stopping FYCOMPA suddenly can cause you to have seizures more often.

What is FYCOMPA?

FYCOMPA is a prescription medicine that is used with other medications to treat partial-onset seizures with or without secondarily generalized seizures in people with epilepsy who are 12 years of age and older.

FYCOMPA is a controlled substance (CIII) because it can be abused or lead to drug dependence. Keep your FYCOMPA in a safe place to protect it from theft. Never give your FYCOMPA to anyone else because it may harm them. Selling or giving away this medicine is against the law.

It is not known if FYCOMPA is safe and effective in children under 12 years of age.

What should I tell my healthcare provider before taking FYCOMPA?

Before you take FYCOMPA, tell your healthcare provider if you:

- have or have had depression, mood problems, aggressive or hostile behavior (for example homicidal behavior), suicidal thoughts or behavior, or other psychiatric problems
- have liver or kidney problems
- drink alcohol
- have abused prescription medicines, street drugs, or alcohol in the past
- have any other medical problems
- are pregnant or plan to become pregnant. It is not known if FYCOMPA will harm your unborn baby.
 - If you become pregnant while taking FYCOMPA, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of FYCOMPA and other antiepileptic medicine during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if FYCOMPA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take FYCOMPA. You and your healthcare provider should decide if you will take FYCOMPA or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Taking FYCOMPA with certain other medicines can cause side effects or reduce either drug's benefit. **Especially tell your healthcare provider if you take:**

- oral contraceptives (birth control pills). FYCOMPA may lower your oral contraceptive's ability to prevent pregnancy if your oral contraceptive contains levonorgestrel.
- carbamazepine (CARBATROL[®], TEGRETOL[®], TEGRETOL-XR[®], EQUETRO[®], EPITOL[®])
- phenytoin (DILANTIN[®], PHENYTEK[®])
- oxcarbazepine (TRILEPTAL[®])
- rifampin (RIFADIN[®], RIMACTANE[®])
- St. John's Wort

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist each time you get a new medicine.

How should I take FYCOMPA?

- Take FYCOMPA exactly as your healthcare provider tells you. Your healthcare provider will tell you how much FYCOMPA to take and when to take it. FYCOMPA is usually taken 1 time a day at bedtime.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- Talk to your healthcare provider about what to do if you miss 1 or more doses of FYCOMPA.
- If you take too much FYCOMPA, call your local Poison Control Center or go to the nearest hospital emergency room right away.

What should I avoid while taking FYCOMPA?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how FYCOMPA affects you. FYCOMPA may make you dizzy, sleepy or tired.
- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking FYCOMPA until you talk to your healthcare provider. FYCOMPA taken with alcohol or medicines that cause sleepiness or dizziness may make your sleepiness or dizziness worse.

What are the possible side effects of FYCOMPA?

See **"What is the most important information I should know about FYCOMPA?"**

FYCOMPA may cause other serious side effects, including:

- **Dizziness, vertigo (sense of spinning) and problems walking normally.** You may have problems walking normally if you are unsteady because you feel dizzy. These symptoms can increase when your dose of FYCOMPA is increased. Your risk of feeling dizzy and having problems walking normally may be higher if you are elderly.
- **Sleepiness and tiredness.** See **“What should I avoid while taking FYCOMPA?”**
- **Increased risk of falls.** Taking FYCOMPA can increase your chance of falling. These falls can cause serious injuries. Your risk of falling may be higher if you are elderly.

The most common side effects of FYCOMPA include:

- dizziness
- sleepiness
- tiredness
- irritability
- falls
- nausea
- problems with muscle coordination
- problems walking normally
- vertigo (sense of spinning)
- weight gain

Tell your healthcare provider about any side effect that bothers you or does not go away.

These are not all of the possible side effects of FYCOMPA. For more information ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store FYCOMPA?

Store FYCOMPA at room temperature between 59°F to 86°F (15°C to 30°C).

Keep FYCOMPA and all medicines out of the reach of children.

General information about the safe and effective use of FYCOMPA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FYCOMPA for a condition for which it was not prescribed. Do not give FYCOMPA to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about FYCOMPA. If you would like more information, talk with your healthcare provider. You can ask

your pharmacist or healthcare provider for information about FYCOMPA that is written for health professionals.

For more information, go to www.FYCOMPA.com or 1-888-274-2378.

What are the ingredients in FYCOMPA?

Active ingredient: perampanel

Inactive ingredients: lactose monohydrate, low substituted hydroxypropyl cellulose, povidone, microcrystalline cellulose, magnesium stearate, hypromellose, polyethylene glycol, talc and titanium dioxide. Tablets of different strengths also may contain yellow ferric oxide (10 mg and 2 mg), red ferric oxide (2 mg, 4 mg, 6 mg, 8 mg), and black ferric oxide (8 mg) and FD&C blue # 2 indigo carmine aluminum lake (10 mg and 12 mg).

This Medication Guide has been approved by the U.S. Food and Drug Administration

Manufactured and Marketed by Eisai Inc., Woodcliff Lake, NJ 07677

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