



Doctor Discussion Guide

Lennox-Gastaut syndrome (LGS) can be one of the most difficult forms of epilepsy to treat, and it can be frustrating to try therapy after therapy with varying outcomes. However, knowing what information to provide, and what questions to ask—can help you and your healthcare team continue to look for additional options.

Providing the Right Information

Give your healthcare team as much information as you can to paint a clear picture of your loved one's condition.

Current treatment plan

- Tell your doctor about the prescription and over-the-counter medications (including vitamins and herbal products) your loved one is taking and how often he or she is taking them.
- Tell your doctor if your loved one has had any other types of medical or nonmedical treatment, such as speech or behavioral therapy, or if he or she is on a ketogenic diet (a diet high in fats and low in carbohydrates).

Current level of seizure activity

- Tell your doctor about the type(s) of seizures your loved one is experiencing and how often they occur.
- If the number of seizures has lessened since starting current treatment, let your doctor know. If your loved one's treatment plan isn't working as well as you would like, speak up. Don't settle.

Side effects

- Explain any medication-related side effects your loved one may be experiencing.

Daily life

- Tell your doctor about any developmental successes or limitations your loved one is currently experiencing.
- Talk about the activities your loved one is involved in and if he or she attends school or has a job. The more your healthcare team knows about your loved one's abilities and activities, the better they can assess potential goals for treatment.

Concerns

- Explain your concerns, and if possible, how your doctor can help. For example, if you're concerned about developmental delays, talk to your doctor about what you can expect based on your loved one's circumstances and ask him or her to recommend a speech or physical therapist who is knowledgeable about LGS.

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Along this journey, you have to be your child's advocate. What we've learned is to explore every available treatment option since there is no real way of knowing what is going to make a difference.

—Dale, father of Adam, 13

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Please see Use and Important Safety Information, including Boxed Warning for risks from concomitant use with opioids on page 3.

Asking the Right Questions

You never know what's going to make a difference in your loved one's life. That's why it's important to ask the right questions and continue to strive for better seizure management.

Exploring treatment options

Most people with LGS take several different antiepileptic medications, and the medications may change as seizure types change. It's important to stay on top of the latest research and available treatment options. Talk to your doctor about what treatments may be right for your loved one.

Consider asking:

- Given my loved one's medical history, are there additional treatment options to consider for LGS?
- Are there nonmedical treatments that could help (eg, occupational, speech, or behavioral therapy)?
- Is it common to take multiple seizure medications at the same time, including those for LGS?
- What should I know about the risks associated with taking seizure medications?
- How can we continue to work best together?

Considering ONFI® (clobazam) CIV

If you're not satisfied with your loved one's current treatment plan, it may be time to ask your neurologist about ONFI. ONFI is a prescription medicine used along with other medicines to treat seizures associated with LGS in adults and children 2 years of age or older.

Do not take ONFI if you have a known allergy to ONFI or its ingredients.

Be sure to ask:

- Can adding ONFI to my loved one's current medications help reduce seizures?
- What is the most important information I should know about ONFI?
- What can we expect in terms of side effects?
- Is it OK for my loved one to take ONFI?
- How often is ONFI taken?
- How will we know if ONFI is working?
- Is financial support available for an ONFI prescription?

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“If there is an LGS option that you've heard about, ask your doctor if it may be appropriate for your child.

—Jackie, mother of Addie, 16

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Please see Use and Important Safety Information, including Boxed Warning for risks from concomitant use with opioids on page 3.

Use

ONFI (clobazam) CIV is a prescription medicine used along with other medicines to treat seizures associated with Lennox-Gastaut syndrome in people 2 years of age or older.

Important Safety Information

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS

See Medication Guide and full Prescribing Information for complete information.

ONFI is a benzodiazepine medicine. Benzodiazepines can cause severe drowsiness, breathing problems (respiratory depression), coma, and death when taken with opioid medicines.

- **Do not take ONFI if you have a known allergy to ONFI or its ingredients.**
- **ONFI can make you sleepy or dizzy and slow your thinking and motor skills. This may get better over time.** Do not drive, operate heavy machinery, or do other dangerous activities until you know how ONFI affects you. ONFI may cause problems with your coordination, especially when you are walking or picking things up.
- **Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking ONFI without first talking to your healthcare provider.** ONFI may make your sleepiness or dizziness much worse.
- **ONFI can cause withdrawal symptoms. Do not suddenly stop taking ONFI without first talking to a healthcare provider.** Stopping ONFI suddenly can cause seizures that will not stop (status epilepticus), hearing or seeing things that are not there (hallucinations), shaking, nervousness, and stomach and muscle cramps.
- **ONFI can be abused and cause dependence.** Physical dependence is not the same as drug addiction. Talk to your healthcare provider about the differences. **ONFI is a federally controlled substance (CIV) because it can be abused or lead to dependence.**
- **Serious skin reactions have been seen when ONFI is taken with other medicines and may require stopping its use.** A serious skin reaction can happen at any time during your treatment with ONFI. Call your healthcare provider immediately if you have skin blisters, rash, sores in the mouth, hives or any other allergic reaction.

- **Like other antiepileptic drugs, ONFI may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.** Call your healthcare provider right away if you have any symptoms of depression, especially sudden changes in mood, behaviors, thoughts, or feelings, and especially if they are new, worse, or worry you.
- **Tell your healthcare provider about all your medical conditions,** including liver or kidney problems, lung problems (respiratory disease), depression, mood problems, or suicidal thoughts or behavior.
- If you are pregnant or plan to become pregnant, **ONFI may harm your unborn baby.** You and your healthcare provider will have to decide if you should take ONFI while you are pregnant.
- ONFI can pass into breast milk. You and your healthcare provider should decide if you will take ONFI or breastfeed. You should not do both.
- **Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking ONFI with certain other medicines can cause side effects or affect how well they work. ONFI may make your birth control medicine less effective. Talk to your healthcare provider about the best birth control method to use. Do not start or stop ONFI or other medicines without talking to your healthcare provider.
- ONFI oral suspension should be kept in its original bottle in an upright position and used within 90 days of first opening the bottle. After 90 days, safely throw away any unused ONFI oral suspension.
- The most common side effects of ONFI include: sleepiness; drooling; constipation; cough; pain with urination; fever; acting aggressive, being angry or violent; difficulty sleeping; slurred speech; tiredness; and problems with breathing.

For more information, please see the [Medication Guide; full Prescribing Information, including Boxed Warning for risks from concomitant use with opioids; and Instructions for Use.](#)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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