

For patients 4 years and older with seizures associated with Lennox-Gastaut syndrome (LGS) who need additional treatment

## Additional Seizure Control May Be Within Reach



## Introducing BANZEL®

This brochure will help you understand seizures associated with Lennox-Gastaut syndrome (LGS) and why prescription BANZEL may offer hope to you or your loved one. It also will provide important information, including:

- What you or your loved one can expect from treatment with BANZEL, including risks
- How to take BANZEL
- Side effects that you or your loved one may experience with BANZEL

You are encouraged to discuss the following with your healthcare provider:

- Important Safety Information on pages 8 and 9
- Medication Guide that is included in the enclosed Package Insert

## What is LGS?

LGS is a rare and severe form of epilepsy. It is a condition that affects the brain. LGS occurs in 1%–4% of children who have epilepsy. It tends to happen in boys more than girls. LGS usually begins to develop before a child is 5 years old. It can be caused by a problem with how the brain was formed, lack of oxygen to the brain (perhaps during pregnancy or delivery), severe head injury, infection affecting the brain, or other conditions. In 30%–35% of cases, no cause can be found.

It is often characterized by the following:

- Experiencing several seizure types and sometimes many seizures in a day (see “What is a seizure?” for more information)
- Delayed intellectual development
- A distinct brain-wave pattern

## What is a seizure?

A seizure is a sudden episode of electrical activity in the brain that can change a person's physical movements or behavior. There are different types of seizures. What occurs during an episode depends on the area of the brain involved.

The types and number of seizures a person experiences may change as the person gets older. However, LGS usually continues through adulthood. At this time, there is no cure for LGS, but researchers continue to try to find treatments that can offer hope.

Most common seizure types	
Seizure type	Description
<b>Atonic</b>	Brief loss of muscle tone and consciousness, causing falls
<b>Tonic</b>	Stiffening of muscles lasting a few seconds up to a minute
<b>Atypical absence</b>	Staring spells lasting for many seconds
<b>Myoclonic</b>	Sudden jerking of the muscle
<b>Partial</b>	Abnormal movement or sensation, change in vision, or other symptoms
<b>Nonconvulsive status epilepticus</b>	Continuous seizure activity that changes a person's level of awareness

BANZEL® is indicated for adjunctive treatment of seizures associated with LGS in children 4 years and older and adults.

**Please see Important Safety Information on pages 8 and 9 and full Package Insert enclosed.**



## Living with seizures

While medications can help reduce the number of seizures a person with LGS may have, complete freedom from seizures is extremely rare for people with LGS. You or your loved one may find the following tips helpful in coping with the challenges of life with LGS.

- You or your loved one may wear a helmet to help prevent injuries, especially during drop seizures that may cause falls
- You may choose to make changes in your home for added safety. This could include installing tub rails or seats, lowering the temperature on the household's water to help prevent burns, or using an intercom system to help detect sounds that a seizure is occurring

- It is important to keep a seizure diary. Include when and what type of seizure occurred, how long it lasted, and any triggers that may have led to the seizure (such as a change in sleep or eating patterns, stress, or a missed dose of medication). This will help in monitoring if the condition is getting better or worse. It also can help you discover triggers that you could try to avoid to help prevent seizures
- If you are the primary caregiver of someone with LGS, it may be beneficial to arrange for outside help to watch your loved one either on a set schedule or when there is a special need. This way you can be assured he or she is getting the appropriate care while you are away for work, errands, or personal time

## Treatments that can help control seizures

Medication is the primary treatment healthcare providers recommend to reduce seizures associated with LGS. In addition to medications, your healthcare provider may advise you about other treatments that can help control seizures such as:

Treatment	Description
<b>Ketogenic diet</b>	A special high-fat, low-carbohydrate diet that has been found to help reduce seizures in some people with epilepsy
<b>Vagus nerve stimulation (VNS) therapy</b>	This sends mild pulses of electrical energy to the brain using the vagus nerve to help prevent seizures
<b>Corpus callosotomy surgery</b>	The large fiber that connects the 2 sides of the brain is cut to help reduce seizures

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## What to expect from medications

Although LGS is difficult to treat, there are medications that can help control seizures experienced with this condition. Your healthcare provider will advise you about medications to help reduce the number of seizures you or your loved one is having. These medications also may make seizures less severe when they do occur. It is common for a person with LGS to be treated with more than one medication at a time in order to provide more seizure control.

You and your healthcare provider should discuss treatment goals before a new medication is prescribed. Your healthcare provider will consider several factors in addition to the goals you discuss before recommending a medication.

He or she will try to prescribe a treatment regimen that will offer the right balance between reductions in seizures and the side effects that may be experienced.

Over time, you or your loved one may have more seizures again. Tell your healthcare provider if this occurs. He or she may recommend changes to the treatment, including a different medication.

## BANZEL® could offer hope

BANZEL is a prescription medication that, when it's added to patients' current therapies, has been clinically proven to reduce seizures that are seen in LGS. A study of patients with LGS showed that when BANZEL was added to therapy, patients had 33% fewer seizures overall. Patients who were treated with their current therapy plus placebo (sugar pill with no medicine in it) in the study had only 12% fewer seizures overall. This included all seizures that were tracked during the study, including seizures that were mentioned earlier in this brochure, such as:

- Atonic
- Tonic
- Myoclonic
- Atypical absence
- Partial

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The types of seizures that can cause a person to suddenly fall can be very upsetting because he or she can be injured during the fall. Since these seizures are of particular concern, the study looked specifically at these kinds of seizures (tonic-atonic). The results showed that when BANZEL was added to patients' current therapy, they experienced a 43% decrease in these seizures, while patients who were treated with placebo plus their current therapy experienced a 2% increase in these seizures.

Also during the study, parents or guardians were asked to assess the severity of patients' seizures to see if there was any change when BANZEL was added to patients' current therapy. According to their observations, more patients



treated with BANZEL® had an improvement in seizure severity than patients who were treated with placebo plus their current therapy.

The results shown in this study may help you determine how BANZEL may offer hope to you or your loved one. However, everyone is unique, so different people may have different results. Talk to your healthcare provider to get more information.

### Important Safety Information

**There are risks associated with the use of BANZEL that you should know about. We encourage you to talk to your healthcare provider about these risks.**

- Patients with a history of Familial Short QT syndrome should not be treated with BANZEL. Talk to your healthcare provider if you are unsure if this affects you or your loved one.

- All medications to treat seizures, including BANZEL, 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 or your loved one experiences new or worsening symptoms of depression, unusual changes in mood or behavior, thoughts or actions about suicide or self-harm, aggression, agitation, anger, anxiety, or irritability.
- Use of BANZEL has been associated with side effects such as sleepiness or feeling tired, difficulty with coordination, dizziness, and problems with walking or movement.
  - Alcohol, in combination with BANZEL, may increase or worsen these side effects.
- Call your healthcare provider if you or your loved one experiences a rash. This can be a sign of a more serious condition, such as multi-organ hypersensitivity reaction.

- You or your loved one should take BANZEL® only as prescribed. Do not stop taking BANZEL without first talking to your healthcare provider. Stopping BANZEL suddenly can cause serious problems.
- Tell your healthcare provider about all the medications you or your loved one takes, including prescription and nonprescription medications, vitamins, and herbal supplements. Using BANZEL with certain medications can affect each other, causing side effects.
- In studies, the most commonly observed side effects were headache, dizziness, feeling tired, sleepiness, and nausea. Most of these side effects were mild to moderate in severity and typically went away in a short amount of time.

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**Please see full Package Insert enclosed.**

### Important information for women

BANZEL may make hormonal contraceptives (birth control pills) less effective. Additional nonhormonal forms of birth control are recommended when using BANZEL.

Healthcare providers should be informed if patients are pregnant or planning on becoming pregnant. Also, BANZEL is likely to be passed through breast milk to the baby and could cause serious side effects in the baby. A decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Patients who are pregnant are encouraged to enroll in the North American Antiepileptic Drug Pregnancy Registry. This can be done by calling the toll-free number 1-888-233-2334. Additional information about the registry can be found at [www.aedpregnancyregistry.org](http://www.aedpregnancyregistry.org).

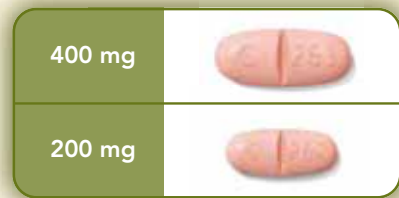


## How to take BANZEL®

BANZEL is available in 200-mg and 400-mg strengths. Your healthcare provider will determine what dose is right for you or your loved one, when the dose should increase or decrease, and by how much. This may help provide the best reduction in seizures with the lowest chance of side effects. It is important to follow the healthcare provider's instructions exactly. A schedule is included in the back of this brochure to help you.

Also, please note:

- BANZEL should be taken by mouth with food
- BANZEL can be crushed
- BANZEL can be cut in half



Tablets are shown at actual size.

## Questions for your healthcare provider

If you have a question about LGS, BANZEL®, or the BANZEL Medication Guide, please ask your healthcare provider. You also may find it helpful to ask your healthcare provider some of the following questions.

- What should I do if I or my loved one misses a dose of medication?
- What should I do if I or my loved one experiences a side effect with BANZEL?
- Could certain vitamins, dietary supplements, or other medications affect how medications for seizures work?
- Could a special diet help me or my loved one?
- Could surgery help me or my loved one and, if so, what are the risks?

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## Additional resources for BANZEL

A Patient Assistance Program is available for patients who do not have insurance or other third-party payor prescription drug coverage, including Medicaid or Medicare. For more information, please call:

### Patient Assistance Program

**Phone: 1-866-694-2550**

**Fax: 1-866-801-5631**

**Hours: 8 AM–7 PM EST, Mon.–Fri. for agent**

### General information

**[www.BANZEL.com](http://www.BANZEL.com)**







## How to start BANZEL® therapy\*

	Day _____		Day _____		Day _____		Day _____		Day _____		Day _____		Day _____	
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
No. of Tablets														
Strength (mg)														

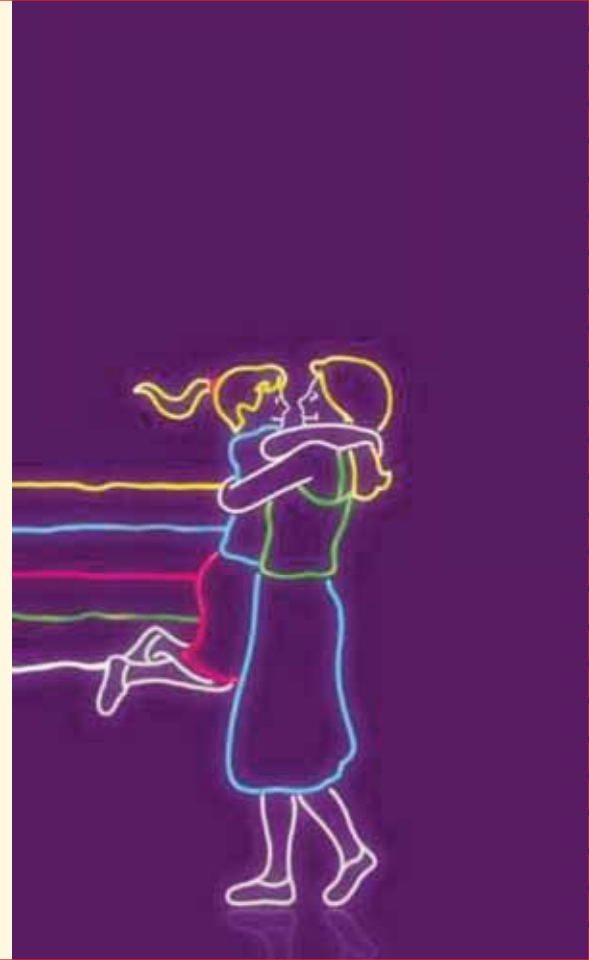
	Day _____		Day _____		Day _____		Day _____		Day _____		Day _____		Day _____	
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
No. of Tablets														
Strength (mg)														

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**BANZEL**<sup>®</sup>  
(rufinamide) <sup>200, 400mg</sup>  
TABLETS