

Medication Guide

BANZEL™ (ban-‘zel)

[rufinamide]

BANZEL and Suicidal Thoughts or Actions

Read this Medication Guide before you start taking BANZEL 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. This Medication Guide is only about the risk of suicidal thoughts and actions with BANZEL.

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

- 1. BANZEL may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.**
- 2. 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
- 3. Do not stop BANZEL without first talking to a healthcare provider.**
 - Stopping BANZEL suddenly can cause serious problems.
 - 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.
- 4. 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.

What else should I know about BANZEL?

- **BANZEL has other side effects.** For more information ask your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effect that bothers you.

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

- **BANZEL can interact with other medicines.** Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Using BANZEL with certain other medicines can affect each other causing side effects.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist each time you get a new medicine. Do not start a new medicine without first talking with your healthcare provider.

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

This Medication Guide summarizes the most important information about BANZEL. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about BANZEL that is written for health professionals.

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

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

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