

# Rufinamide (BANZEL®): the basics

## What is rufinamide used for?

Rufinamide has been approved by Health Canada for use in combination with other anti-seizure (anti-epileptic) medications to manage seizures associated with **Lennox-Gastaut syndrome** in people aged 4 years and older.

Your physician may decide to prescribe this medication for a use different from that approved by Health Canada.

If you have questions about whether this medication is appropriate for you, consult with your physician.

## What forms does this medication come in? Is there a generic drug version?

In Canada, rufinamide is sold under the brand name Banzel®; it is not available as a generic drug.

Dosage form	Strengths available in Canada	Is it covered by the Ontario Drug Benefit (ODB) program?*
Tablets, oral	100 mg, 200 mg, and 400 mg	Rufinamide is not routinely covered by ODB; coverage may be considered under exceptional circumstances. Consult your healthcare professional for more information.

\*Contact your pharmacist for the most up-to-date information regarding drug availability and coverage.

## Before starting rufinamide, inform your healthcare professional of the following:

- your medical history, especially of allergies; heart, kidney, liver, or mental health problems; or blood disorders
- if you have a heart rhythm disorder called familial short QT syndrome
- if your family members have a heart rhythm disorder called short QT syndrome
- if you have an allergy or sensitivity to triazole derivatives, such as fluconazole
- if you are pregnant, breastfeeding, or considering pregnancy
- any anti-seizure medications you have used in the past
- your current medications (prescription and nonprescription) and any substances you are taking

## Rufinamide may interact with the following:

- **other anti-seizure medications**, such as carbamazepine, phenobarbital, valproic acid, and phenytoin. Your physician may need to adjust the doses of your anti-seizure medications.
- **medications and substances that slow down the nervous system (CNS depressants)**, including alcohol and other anti-seizure medications. These may increase the risk of side effects, such as drowsiness or slowed breathing. Limit or avoid drinking alcohol while on rufinamide.
- **hormonal contraceptives** (such as oral contraceptives). These may be less effective when used with rufinamide; consult with your healthcare professional to select the appropriate birth control methods.
- **medications and substances that can affect how your heart beats**, specifically those that may shorten the QT interval on an electrocardiogram (ECG). Digoxin and phenytoin are two examples of such medications.
- **other medications**. This is not a comprehensive list of drug interactions. Inform your healthcare professional about all the medicines (prescription and nonprescription) or substances you are taking, including medications from other prescribers, over-the-counter medications, vitamins, minerals, herbal products, or alternative medicines, so they can check for potential drug interactions. A potential drug interaction may not rule out use of the medications together; dosage adjustments and/or additional monitoring (such as lab work) may be carried out by your healthcare professional; check with your physician or pharmacist.

## What are possible side effects from using rufinamide?

Depending on the individual, side effects may occur at varying degrees or not at all, including:

- **dizziness, drowsiness, and other side effects that can affect your cognition, alertness, coordination, or vision**. It is important to avoid activities requiring mental alertness or physical coordination (such as operating hazardous machines or driving) until you are sure that rufinamide does not affect your abilities.
- **heart rhythm problems**, specifically shortening of the QT interval on an ECG. If you have a history of heart disease, tell your physician.
- **a lower-than-normal number of white blood cells**. Your blood work may need to be checked on a regular basis.
- **status epilepticus** while taking rufinamide.
- **mood or behaviour changes**, such as thoughts or actions of self-harm, which may occur rarely. If you have thoughts of suicide or harming yourself, seek medical help.
- **rare but serious, life-threatening allergic reactions** that require immediate medical help. These reactions mostly occur during the first few weeks of therapy.

This is not a comprehensive list of possible side effects. Consult with your physician or pharmacist for more information about side effects, including what symptoms to monitor for and what to do about them.

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## Tips for using Rufinamide (Banzel®):

- Take your medication as directed by your physician. Read the medication information sheets given to you by your healthcare professional. If you have any questions, ask your physician or pharmacist.
- This medication works best when taken at evenly-spaced intervals, at about the same times each day.
- Rufinamide should be taken with food.
- The tablets can be swallowed whole, cut in half, or crushed.
- If your seizures worsen or you experience new types of seizures, contact your physician.

## How will my dose be determined?

In general, your physician will start you on a low dose to decrease the risk of side effects. This dose will be adjusted slowly based on seizure control and any side effects experienced. Other factors such as body weight, medical history, and potential drug interactions will also be taken into consideration when determining your dose.

Rufinamide is taken twice a day with food. The maximum daily dose of rufinamide is based on body weight (see the table below).

Weight Range	Under 30 kg	30.0 kg to 50.0 kg	50.1 kg to 70.0 kg	Equal to or more than 70.1 kg
Maximum recommended dose (mg per day)	1300	1800	2400	3200

## What if I miss a dose?

If you miss a dose, take it as soon as you remember. But if it is almost time for your next dose, do not take the missed dose; instead, take your next dose at your usual time. Do not double the dose. If you miss more than 1 dose, contact your healthcare professional for advice.

## How do I store this medication?

Store the rufinamide tablets at room temperature (15 to 30°C) in a dry place away from light and heat. Keep out of reach of children.

## Medication blood level test – is it required for rufinamide?

Routine monitoring of the concentrations (levels) of rufinamide in your blood is usually not required.

## Pregnancy and breastfeeding:

- In general, anti-seizure medications may slightly increase the risk of birth defects. It is important to consult with your healthcare professional for preconception care if you are planning to become pregnant.
- Folic acid supplementation should be started at least 3 months before pregnancy to reduce the risk of birth defects. Speak with your healthcare professional to determine the appropriate dose for you.
- There is very limited data on the use of rufinamide during pregnancy or breastfeeding. The potential benefits of using this medication during pregnancy or breastfeeding must be weighed against any potential risks to your unborn child or breastfed baby; consult with your physician. Do not stop taking your medication(s) or adjust your dosage on your own.

## Warning:

Abrupt withdrawal of any anti-epileptic medication may trigger status epilepticus, a potentially fatal condition of continued seizures without recovery. When there is a need for reduction, discontinuation or substitution of the medication, this should be done gradually and under the physician's care. Never discontinue anti-epileptic medications or make changes in activities unless specifically advised to do so by an attending physician.

This material has been created by Stephanie Chiu, RPh, BCGP, CDE for Epilepsy Toronto in 2024 and is offered to provide general information to the public. It is not intended to be taken as medical advice. Epilepsy Toronto and its advisors accept no liability. Consult your physician and/or neurologist with any questions you may have.