

# Ministry of Health and Long-Term Care

## Ontario Public Drug Programs

### Drug Submission Status

<b>Generic Name:</b>	rufinamide
<b>Brand Name:</b>	Banzel
<b>Strength:</b>	100mg, 200mg and 400mg tablet
<b>Manufacturer:</b>	Eisai Limited
<b>Indication:</b>	For adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in children 4 years and older and adults
<b>Rapid Review:</b>	Not requested

<b>Submission Type:</b>	<b>Date Submission Received:</b>	<b>Date Submission Deemed Complete:</b>	<b>Review Status:</b>	<b>Funding Decision:</b>
First Review (Initial Submission)	21/03/2012	17/04/2012	EO decision rendered	Funding considered through the Exceptional Access Program (EAP)

**Rapid Review:**

Details of the Rapid Review process can be found at:

[www.health.gov.on.ca/english/providers/program/drugs/drug\\_submissions/rapid\\_review\\_process.html](http://www.health.gov.on.ca/english/providers/program/drugs/drug_submissions/rapid_review_process.html)

**Review Status:**

- Screening – Ministry is screening the manufacturer's submission to ensure all regulatory and policy requirements have been met in order to proceed with the drug review.
- Submission incomplete – Manufacturer did not meet the necessary requirements to allow review to proceed.
- Submission complete & under review – Manufacturer met all requirements to proceed with the drug review, and evaluation of the drug submission is underway.
- Committee to Evaluate Drugs (CED) review completed, manufacturer requesting reconsideration – A recommendation was made by the CED, however the manufacturer has submitted or will be submitting additional information.
- Committee to Evaluate Drugs (CED) review completed – A recommendation was made by the CED.
- Executive Officer (EO) decision rendered.

**Funding Decision:**

The Committee to Evaluate Drugs (CED) recommendation and the Executive Officer (EO) decision can be found at: [www.health.gov.on.ca/english/providers/program/drugs/ced\\_rec\\_table.html](http://www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html)

Updated: July 25, 2012

