Briviact

(brivaracetam)

New Product Slideshow

MPR

Introduction

- **Brand name:** Briviact
- **Generic name:** Brivaracetam
- **Pharmacological class:** Antiepileptic
- **Strength and Formulation:** 10mg, 25mg, 50mg, 75mg, 100mg tabs; 10mg/mL oral solution (raspberry flavored); 50mg/5mL solution for IV injection
- **Manufacturer:** UCB
- **How supplied:** Tabs—60; Oral solution—300mL; Single-dose vials—10
- **Legal Classification:** CV

Indications

- **Oral:** adjunctive treatment of partial-onset seizures
- **Injection:** adjunctive treatment of partial-onset seizures when oral administration is temporarily not feasible

Dosage & Administration

- All forms can be used interchangeably
- **Tabs:** swallow tabs whole with liquid
- **Oral solution:** use calibrated measuring device; may also give via nasogastric or gastrostomy tube
- **IV:** Give over 2–15 minutes; limit to 4 consecutive days of treatment

Dosage & Administration

- **≥16yrs:** initially 50mg twice daily; may adjust down to 25mg twice daily or up to 100mg twice daily based on response and tolerability
- **Hepatic impairment:** initially 25mg twice daily; max 75mg twice daily
- **Concomitant rifampin:** double brivaracetam dosage

Considerations for Special Populations

- **Pregnancy:** Category C
- **Nursing mothers:** Not recommended
- **Pediatric:** <16yrs: not established
- **Geriatric:** Insufficient number studied
- **Hepatic impairment:** See Dosing
- **Renal impairment:** ESRD undergoing dialysis: not recommended

Warnings/Precautions

- **Increased risk** of suicidal behavior or ideation; monitor for clinical worsening and/or any unusual changes
- **Monitor** for neurological and psychiatric adverse reactions
- **Discontinue** if hypersensitivity reactions occur
- **Avoid** abrupt cessation

Interactions

- Antagonized by **rifampin** (see Dosing)
- Concomitant **carbamazepine**: may consider dose reduction if intolerant
- May potentiate **phenytoin**; monitor phenytoin levels when adding or discontinuing brivaracetam from ongoing therapy
- Concomitant **levetiracetam**: no added benefit

Adverse Reactions

- Somnolence/sedation
- Dizziness
- Fatigue
- Nausea/vomiting
- Hematologic abnormalities

Mechanism of Action

- The precise mechanism by which brivaracetam exerts its anticonvulsant activity is unknown
- It displays a high and selective affinity for synaptic vesicle protein 2A (SV2A) in the brain, which may contribute to its anticonvulsant effect

Pharmacokinetics

- **Metabolism:** Hydrolysis
- **Elimination:** Renal

Clinical Trials

- The efficacy of Briviact as adjunctive treatment in partial-onset seizures with or without secondary generalization was established in **Studies 1, 2, and 3**
- All 3 trials were fixed-dose, randomized, double-blind, placebo-controlled, multicenter studies involving 1,550 patients with partial-onset seizures inadequately controlled with 1 to 2 concomitant antiepileptic drugs (AEDs)
- All trials included an 8-week baseline period, followed by a 12-week treatment period

Clinical Trials

- **Study 1** compared doses of Briviact 50mg/day and 100mg/day with placebo
- **Study 2** compared a dose of Briviact 50mg/day with placebo
- **Study 3** compared doses of Briviact 100mg/day and 200mg/day with placebo
- Briviact was administered in equally divided twice daily doses
- Upon termination of Briviact therapy, patients were down-titrated over a 1-, 2-, and 4-week duration for patients receiving 25mg, 50mg, and 100mg twice daily, respectively

Clinical Trials

- The **primary efficacy endpoint** was the percent reduction in 7-day partial-onset seizure frequency over placebo for Studies 1 and 2, and the percent reduction in 28-day partial-onset seizure frequency over placebo for Study 3

Clinical Trials

- In **Study 1**, the percent reduction in partial-onset seizure frequency over placebo was 9.5% for the 50mg/day dose and 17% for the 100mg/day dose
- **Study 2** demonstrated a 16.9% reduction in partial-onset seizure frequency for the 50mg/day dose over placebo ($P<0.05$)

Clinical Trials

- **Study 3** demonstrated a statistically significant seizure frequency reduction for Briviact over placebo, with 25.2% and 25.7% reduction for the 100mg/day and 200mg/day dosing, respectively ($P<0.05$)

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/briviact/drug/34552/