



King Faisal General Hospital

P&T Committee Drug Evaluation Monograph

[Drug Name: ()]

Requested by:

Date of Request:

Department:

Reason for Evaluation:

Prepared by:

Is conflict of interest declared: Yes NO

Therapeutic Class:

Manufacturer:

Similar Drugs available at KFGH formulary: [List all applicable]

| Similar Drugs |
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Approval Status:

| | | | | |
|---|--|--|---|---|
| <input checked="" type="checkbox"/> USA | <input checked="" type="checkbox"/> UK | <input checked="" type="checkbox"/> Canada | <input checked="" type="checkbox"/> EMA | <input checked="" type="checkbox"/> KSA |
|---|--|--|---|---|

| Drug Information | |
|---|--|
| Mechanism of Action | |
| Requested Indication | |
| (approved/unapproved) | |
| Route of Administration | |
| Dosage Forms | |
| Dose | |
| Adjustment required in specific population | <input type="checkbox"/> Liver <input type="checkbox"/> Renal <input type="checkbox"/> Not studied <input type="checkbox"/> Others, specify |
| Indicator for pediatrics | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Studied <input checked="" type="checkbox"/> Age group out off |
| Pharmacokinetics | |
| Absorption | |
| Distribution | |
| Time to Peak | |
| Metabolism | |
| Excretion | |
| Half Life | |
| Others | |
| SAFETY | |



| | |
|--|---|
| Common Adverse Reactions (%) | |
| Serious adverse Reactions (%) | |
| Drug interactions | |
| Contraindications / Precautions | |
| Monitoring Requirements | |
| Sound-Alike/ Look-Alike | |
| Boxed warning or alerts issued | |
| High Alert | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |
| Handling | <input type="checkbox"/> Hazardous/cytotoxic Precaution <input checked="" type="checkbox"/> None • Others..... |
| Cost | |
| Cost/pack | |
| Cost/patient/month (or treatment course) | |



PHARMACY AND THERAPEUTIC COMMITTEE
DRUG EVALUATION: [Brivaracetam (Briviact®)]

Table 1: Summary of Published Evidence (Efficacy & Safety)

| Ref | Design* | Drug regimens | n | Duration | Outcome Measures | Demographics | Results/Comments | NT |
|-----|---------|---------------|---|----------|------------------|--------------|------------------|----|
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***Study design abbreviations:** DB=Double Blind, RTC=Randomized Control Trial, PC=Placebo Controlled, PG=Parallel Group, XO=Crossover, MC=Multi-center.
NNT (Number needed to treat)=100/Absolute risk reduction, calculated only if P value less than 0.05 (i.e.: statistically significant)

Table 2: Summary of Pharmacoeconomic Studies (if available)

| Ref | Drug/Treatment Arms | n | Duration | Method * | Outcome Measures | Cost Measures | Results/Comments |
|-----|---------------------|---|----------|----------|------------------|---------------|------------------|
| 1. | | | | | | | |
| 2. | | | | | | | |

***Method abbreviations:** CEA=cost- effective analysis, CUA=cost-utility analysis, CBA=cost- benefit analysis, CCA=cost-consequence analysis.

No pharmacoeconomic studies have been published in Saudi Arabia



PHARMACY AND THERAPUETIC COMMITTEE
DRUG EVALUATION: [Generic name:)]

Summary of evidence:

| | |
|---|---|
| Efficacy/Safety (details table 1) | |
| | |
| Pharmacoeconomic (details table 2) | |
| | |
| Level 1a | <i>Systematic review of a randomized controlled trial</i> |
| Level 1b | <i>Individual randomized controlled trial</i> |
| Level 2a | <i>Systematic review of cohort studies</i> |
| Level 2b | <i>Individual cohort study</i> |
| Level 3a | <i>Systematic review of case-controlled studies</i> |
| Level 3b | <i>Individual case-control study</i> |
| Level 4 | <i>Case series</i> |
| Level 5 | <i>Expert opinion</i> |

| | |
|----------|---|
| A | <i>There is good evidence to support the recommendation</i> |
| B | <i>There is fair evidence to support the recommendation</i> |
| C | <i>There is poor or no evidence to support the recommendation</i> |

Levels of Evidence: Grades of Recommendations

Summary of the evaluation:

| Pros | Cons | Uncertainty |
|------|------|-------------|
| | | |

Prepared by:

Date: / /2025

Reviewed by:

References: