

# GABA®

Gabapentin USP

## PRESENTATION:

**GABA® 300mg tablet:** Each film coated tablet contains 300mg Gabapentin USP.

## INDICATIONS:

### Epilepsy:

- Adjunct for treatment of partial seizures with and without secondary generalized seizures in patients > 12 years of age with epilepsy,
- Adjunct for treatment of partial seizures in pediatric patients 3-12 years of age.

### Neuralgia:

Gabapentin is indicated for the management of post-herpetic neuralgia in adults. It is also used for the treatment of neuropathic pain and trigeminal neuralgia.

**Unlabeled Use** Bipolar disorder, social phobia, chronic pain.

## DOSAGE AND ADMINISTRATION

( Oral)

### Children: Anticonvulsant:

**3-12 years:** Initial: 10-15 mg/kg/day in 3 divided doses; titrate to effective dose over ~ 3days; dosages of up to 50 mg/kg/day have been tolerated in clinical studies

**3-4 years:** Effective dose: 40 mg/kg/day in 3 divided doses

**≥ 5-12 years:** Effective dose: 25-35 mg/kg/day in 3 divided doses

(Note: If Gabapentin is discontinued or if another anticonvulsant is added to therapy, it should be done slowly over a minimum of 1 week)

### Children > 12 years and Adults:

**Anticonvulsant:** Initial: 300 mg 3 times/day; if necessary the dose may be increased using 300 mg or 400 mg tablets 3 times/day up to 1800 mg/day

Dosage range: 900-1800 mg administered in 3 divided doses at 8-hour intervals

**Pain (unlabeled use):** 300-1800 mg/day given in 3 divided doses has been the most common dosage range

**Bipolar disorder (unlabeled use):** 300-3000 mg/day given in 3 divided doses;

**Adults: Post-herpetic neuralgia:** Day 1: 300mg, Day 2: 300mg twice daily, Day 3: 300 mg 3 times/day; dose may be titrated as needed for pain relief (range: 1800-3600 mg/day, daily doses > 1800 mg do not generally show greater benefit)

## Gaba® (Gabapentin) Dosing Adjustments in Renal Impairment

Creatinine Clearance (mL/min)	Total Daily Dose Range (mg/day)	Dosage Regimens Based on Renal Function (mg)					
		300 tid	400 tid	600 tid	800 tid	1200 tid	
≥ 60	900-3600	300 tid	400 tid	600 tid	800 tid	1200 tid	
>30-59	400-1400	200 bid	300 bid	400 bid	500 bid	700 bid	
>15-29	200-700	200 qd	300 qd	400 qd	500 qd	700 qd	
<15 <sup>1</sup>	100-300	100 qd	125 qd	150 qd	200 qd	300 qd	
Hemodialysis <sup>2</sup>	Post-Hemodialysis Supplemental Dose						
	125 mg	150 mg	200 mg	250 mg	350 mg		

<sup>1</sup>Cl<sub>cr</sub> <15 mL/minute: Reduce daily dose in proportion to creatinine clearance.

<sup>2</sup>Supplemental dose administered after each 4 hours of hemodialysis (maintenance doses based on renal function).

Elderly: Studies in elderly patients have shown a decrease in clearance as age increases. This is most likely due to age-related decreases in renal function; dose reductions may be needed.

**Dosing adjustment in renal impairment:** Children ≥ 12 years and Adults: See table.

**Dietary Considerations** May be taken without regard to meals.

**Administration** Maximum time interval between multiple daily doses should not exceed 12 hours; administer first dose on first day at bedtime to avoid somnolence and dizziness.

## PRECAUTIONS:

Patients should be instructed to take Gabapentin only as prescribed.

Patients should be advised that Gabapentin may cause dizziness, somnolence and other symptoms and signs of CNS depression. Accordingly, they should be advised neither to drive a car nor to operate other complex machinery until they have gained sufficient experience on Gabapentin whether or not it affects their mental and/or motor performance adversely.

## ADVERSE REACTIONS:

Diarrhea, dry mouth, dyspepsia, nausea, vomiting, peripheral edema, dizziness, drowsiness, anxiety, abnormal gait, amnesia, ataxia, nystagmus, tremor, paresthesia, emotional lability, hyperkinesias, weight gain, dysarthria, arthralgia, diplopia, amblyopia, rash, purpura, less commonly, constipation, flatulence, dyspnea, confusion, impotence, and leucopenia, rarely pancreatitis, depression, psychosis, headache, myalgia, and urinary incontinence, hepatitis, jaundice, chest pain, palpitation, movement disorder, thrombocytopenia, tinnitus, acute renal failure, and alopecia also reported.

## CONTRAINDICATION:

Gabapentin is contraindicated in patients who have demonstrated hypersensitivity to the drug its ingredients.

## DRUG INTERACTION:

Coadministration of Gabapentin decreases hydrocodone C<sub>max</sub> and AUC values by 3% to 4% lower respectively. After administration hydrocodone increases Gabapentin AUC values by 14%. Antacids reduce the bioavailability of Gabapentin by about 20%. Gabapentin is not appreciably metabolized nor does it interfere with the metabolism of commonly coadministered antiepileptic drugs. Cimetidine appeared to alter the renal excretion of Gabapentin.

## USE IN PREGNANCY AND LACTATION:

Gabapentine is a Pregnancy Category C drug. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Gabapentin is secreted into human milk following oral administration. A nursed infant could be exposed to a maximum dose of approximately 1mg/kg/day of Gabapentin. Because the effect on the nursing infant is unknown, Gabapentin should be used in women who are nursing only if the benefits clearly outweigh the risks.

## STORAGE CONDITION:

Store in a cool and dry place, protected from light and children.

## HOW SUPPLIED:

GABA® 300mg Tablet- Each box contains 3 blister strips of 10 tablets.

Manufactured by  
**RENATA LIMITED**  
Mirpur, Dhaka, Bangladesh  
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