Vigabatrin (vee-gah-bat-rin)

**Classification**
Therapeutic: anticonvulsants

**Pregnancy Category C**

**Indications**
Management (adjunctive) of refractory complex partial seizures in patients who have responded inadequately to several alternative treatments (and where potential benefits outweigh risk of vision loss), not a first-line treatment. Management of infantile spasms (IS).

**Action**
Acts as an irreversible inhibitor of \(\gamma\)-aminobutyric acid transaminase (GABA-T), the enzyme responsible for the metabolism of the inhibitory neurotransmitter GABA. This action results in increased levels of GABA in the central nervous system. **Therapeutic Effects:** Decreased incidence and severity of refractory complex partial seizures.

**Pharmacokinetics**
- **Absorption:** Completely absorbed following oral administration.
- **Distribution:** Enters breast milk, remainder of distribution unknown.
- **Protein Binding:** None.
- **Metabolism and Excretion:** Minimal metabolism, mostly eliminated unchanged in urine.
- **Half-life:** 7.5 hr.

**TIME/ACTION PROFILE (anticonvulsant effect)**
<table>
<thead>
<tr>
<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
<th>DURATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PO</td>
<td>unknown</td>
<td>1 hr†</td>
<td>12 hr‡</td>
</tr>
</tbody>
</table>

†blood level
‡clinical benefit should be seen in 2–4 weeks for IS or within 3 months for complex partial seizures

**Contraindications/Precautions**
- **Contraindicated in:** History or high risk of other types of irreversible vision loss unless benefits of treatment clearly outweigh risk. OB: Use only if the potential benefits justify the potential risk to the fetus (may cause fetal harm). Lactation: Enters breast milk; breast feeding should be avoided.

**Use Cautiously in:** Renal impairment (dose modification recommended for CCr \(< 50\) mL/min); History of suicidal ideation; Geri: Consider age-related \(\Uparrow\) risk of sedation/confusion; Pedi: Abnormal MRI signal changes have been seen in infants.

**Adverse Reactions/Side Effects**
- **CNS:** SUICIDAL THOUGHTS, confusional state, memory impairment, drowsiness, fatigue.
- **CV:** Edema.
- **Derm:** STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS.
- **EENT:** Blurred vision, nystagmus, vision loss.
- **Hemat:** Anemia.
- **Metab:** Weight gain.
- **MS:** Arthralgia.
- **Neuro:** Abnormal coordination, tremor, peripheral neuropathy.

**Interactions**
- **Drug-Drug:** Should not be used concurrently with other drugs having adverse ocular effects; \(\Uparrow\) risk of additive toxicity. May \(\Uparrow\) phenytoin levels and effectiveness.

**Route/Dosage**

**Refractory Complex Partial Seizures**
- **PO (Adults and Children \(\geq 16\) yr):** 500 mg twice daily initially, may be \(\Uparrow\) in 500 mg increments every 7 days depending on response up to 1500 mg twice daily.
- **PO (Children 10–16 yr and \(\geq 60\) kg):** 500 mg twice daily initially, may be \(\Uparrow\) in 500 mg increments every 7 days depending on response up to 1500 mg twice daily.
- **PO (Children 10–16 yr and 25–60 kg):** 250 mg twice daily initially, may be \(\Uparrow\) every 7 days depending on response up to 1000 mg twice daily.

**Renal Impairment**
- **PO (Adults and Children \(\geq 10\) yr and \(\leq 25\) kg):** CCr \(\geq 50–80\) mL/min — \(\Uparrow\) dose by 25%; CCr \(\geq 30–50\) mL/min — \(\Uparrow\) dose by 50%; CCr \(\geq 20–30\) mL/min — \(\Uparrow\) dose by 75%.

**Infantile Spasms**
- **PO (Children 1 mo–2 yr):** 50 mg/kg/day given in 2 divided doses initially, \(\Uparrow\) by 25–50 mg/kg/day increments every 3 days up to a maximum of 150 mg/kg/day; dosage adjustments are necessary for renal impairment.
NURSING IMPLICATIONS

Assessment

- Assess location, duration, and characteristics of seizure activity. Institute seizure precautions. Assess response to and continued need for vigabatrin periodically during therapy.
- Monitor closely for notable changes in behavior that could indicate the emergence or worsening of suicidal thoughts or behavior or depression.
- Test vision at baseline (no later than 4 weeks after starting), at least every 3 months during, and 3–6 months after discontinuation of therapy.
- Assess for signs and symptoms of peripheral neuropathy (numbness or tingling or loss of tactile sense, reduced lower limb vibration or position sensation, progressive loss of reflexes, starting at ankles).
- Assess for rash periodically during therapy. May cause Stevens-Johnson syndrome. Discontinue therapy if severe or if accompanied with fever, general malaise, fatigue, muscle or joint aches, blisters, oral lesions, conjunctivitis, hepatitis and/or eosinophilia.

Lab Test Considerations:

- Monitor CBC periodically during therapy. May cause anemia.
- May cause AST and ALT levels precluding use to detect hepatic injury.
- May cause amino acids in urine causing false positive results of genetic metabolic diseases.

Potential Nursing Diagnoses

- Risk for injury (Indications)
- Disturbed sensory perception (Adverse Reactions)

Implementation

- Available only through SHARE program of restricted distribution. Only prescribers and pharmacies registered in the program and patients enrolled in the program have access. Patients receive vigabatrin from a specialty pharmacy. Contact SHARE program at 1-888-45-SHARE.
- PO: Administer twice daily without regard to food.
- Mix oral solution for babies by mixing the powder in each packet with 10 mL of water; may be cold or room temperature. Follow manufacturer’s instruction for mixing oral solution. Oral solution may be administered at the same time as food, but should only be mixed with water.

Patient/Family Teaching

- Enroll patient in SHARE Program. Instruct patient to take tablets around the clock, as directed. Discuss with health care professional what to do if a dose is missed. Medication should be gradually discontinued to prevent seizures. Advise patient to read the Medication Guide before starting therapy and with each Rx refill in case of changes.
- Instruct patient on risks of vigabatrin. Inform patient of the risk of permanent vision loss, particularly loss of peripheral vision, and that vision loss may not be detected before it is severe and is irreversible. Emphasize the importance of monitoring vision every 3 months. Advise patient to notify health care professional immediately of changes in vision (include seeing as well as before starting therapy, blurring, bumping into things, unusual circumstances, failure to see something in front of you that seems out of nowhere) or changes in unusual vision are suspected.
- May cause drowsiness, ataxia, fatigue and confusion. Caution patient to avoid driving or other activities requiring alertness until response to medication is known. Tell patient not to resume driving until physician gives clearance based on control of seizure disorder.
- Instruct patients and families of risk of suicidal thoughts and behavior and advise that behavioral changes, emergency or worsening signs and symptoms of depression, unusual changes in mood, or emergence of suicidal thoughts, behavior, or thoughts of self-harm or rash should be reported to health care professional immediately.
- Advise patient to avoid alcohol and other CNS depressants concurrently with lacosamide.
- Advise female patients to notify health care professional if pregnancy is planned or suspected or if breast feeding. Encourage pregnant patients to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry by calling 1-888-233-2334; information is available at www.aedpregnancyregistry.org.
CONTINUED
vigabatrin

Evaluation/Desired Outcomes
- Decreased seizure activity. If no substantial clinical benefit within 3 months of initiation, discontinue vigabatrin.
- Decreased in infantile spasms. If no substantial clinical benefit within 2–4 wk of initiation, discontinue vigabatrin.

Why was this drug prescribed for your patient?