Clobazam (kloe-ba-zam)

**Classification**
Therapeutic: anticonvulsants
Pharmacologic: benzodiazepines

**Schedule IV**

**Pregnancy Category C**

**Indications**
Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients ≥2 yr.

**Action**
Facilitates neurotransmission mediated by gamma-amino butyric acid (GABA) by binding to the benzodiazepine site of the GABAA receptor.

**Therapeutic Effects:**
Decreased incidence and severity of seizures associated with Lennox-Gastaut syndrome.

**Pharmacokinetics**

**Absorption:** Well absorbed following oral administration.

**Distribution:** Rapidly distributes throughout the body; enters breast milk.

**Metabolism and Excretion:** Extensively metabolized by the liver; 2% excreted unchanged in urine, 1% in feces Mostly metabolized by CYP3A4, some metabolism by CYP2C19 and CYP2B6. Major circulating metabolite, desmethylclobazam, is 1/5 as active as the parent compound and is further metabolized by the CYP2C19. Metabolites of this process are renally eliminated. Poor CYP2C19 metabolizers have significantly higher levels of desmethylclobazam.

**Half-life:**
- Clobazam—36–42 hr
- Desmethylclobazam—71–82 hr

**TIME/ACTION PROFILE (blood levels)**

<table>
<thead>
<tr>
<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
<th>DURATION</th>
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</thead>
<tbody>
<tr>
<td>PO</td>
<td>unknown</td>
<td>0.5–4 hr</td>
<td>12–24 hr</td>
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| Contraindications/Precautions |

**Contraindicated in:**
- None noted.

**Use Cautionfully:**
- Hepatic impairment (dosage adjustment recommended for mild to moderate impairment). History of substance abuse, suicidal behavior/ideation. Geri: Slow dosage escalations and weight based dosing recommended due to higher blood levels. OB: Use in pregnancy only if potential benefit outweighs fetal risks. DDx: Clobazam enters breast milk, effects on infants are not known. Use in pregnancy only if potential benefit outweighs fetal risks. DDx: Clobazam enters breast milk, effects on infants are not known. Use in pregnancy only if potential benefit outweighs fetal risks.

**Adverse Reactions/Side Effects**

**CNS:** somnolence, aggression, ataxia, dizziness, dysarthria, fatigue, insomnia, irritability, lethargy.

**Derm:** STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS.

**Resp:** cough.

**GI:** constipation, drooling, dysphagia, appetite, vomiting.

**Drug Interactions**

**Drug-Drug:** Alcohol: Blood levels by 50%; risk of CNS depression with alcohol, some antidepressants, antihistamines, opioid analgesics and sedative-hypnotics. Concurrent use of strong/moderate inhibitors of the CYP2C19 enzyme system including: fluconazole, fluvoxamine, ticlopidine and omeprazole levels and effects of N-desmethylclobazam; lower doses of clobazam may be necessary.

**Route/Dosage**

**PO (Adults and Children ≥30 kg):** 5 mg twice daily initially, may be titrated after 1 wk to 20 mg/day in 2 divided doses and after another wk to a maximum of 40 mg/day in 2 divided doses.

**PO (Adults and Children ≤30 kg):** 5 mg daily initially, may be titrated after 1 wk to 10 mg/day in 2 divided doses and after another wk to a maximum of 20 mg/day in 2 divided doses.

**PO (Geriatric Patients ≥30 kg):** 5 mg daily initially, may be titrated weekly over 5 wk to a maximum of 40 mg/day in 2 divided doses.

**PO (Geriatric Patients ≤30 kg):** 5 mg daily initially, may be titrated weekly over 5 wk to a maximum of 20 mg/day in 2 divided doses.

**Hepatic Impairment**

**PO (Adults and Children):** Mild to moderate hepatic impairment and weight ≥30 kg—5 mg daily initially, may be titrated weekly over 1 wk to a maximum of 40 mg/day in 2 divided doses. Mild to moderate hepatic impairment and weight <30 kg—5 mg daily initially, may be titrated weekly over 5 wk to a maximum of 20 mg/day in 2 divided doses.

**PO (Adults and Children):** Known CYP2C19 poor metabolizers—5 mg daily initially, may be titrated weekly over 5 wk to a maximum of 40 mg/day in 2 di-
vided doses; known CYP2C19 poor metabolizers
30 kg—5 mg daily initially, may be titrated weekly over 3 wk to a maximum of 20 mg/day in 2 divided doses.

NURSING IMPLICATIONS

Assessment

● Assess location, duration, and characteristics of seizure activity. Institute seizure precautions.
● Monitor closely for notable changes in behavior that could indicate the emergence or worsening of suicidal thoughts or behavior or depression.
● Assess patient for skin rash frequently during therapy. Discontinue at first sign of rash; may be life-threatening.

Lab Test Considerations: May cause anemia, eosinophilia, leukopenia, thrombocytopenia.
● May cause increased hepatic enzymes.

Potential Nursing Diagnoses

Risk for injury (Adverse Reactions)

Implementation

● PO: Administer without regard to meals. Tablets can be administered whole or crushed and mixed with applesauce.
● Use provided measuring device and syringe for accurate measure of oral solution.
● Do not escalate dose more rapidly than 1 week.

Patient/Family Teaching

● Instruct patient to take clobazam around the clock, as directed. Do not stop taking clobazam without consulting health care professional. Medication should be gradually discontinued to prevent withdrawal symptoms (seizures, psychosis, hallucinations, behavioral disorder, tremor, anxiety). Advise patient to read the Medication Guide before starting therapy and with each Rx refill in case of changes.
● Instruct patient to avoid driving or other activities requiring alertness until response to medication is known. Tell patient to resume driving only when physician gives clearance based on control of seizure disorder.
● Instruct patient and family members 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.
● Instruct patient to notify health care professional of all Rx or OTC medications, vitamins, herbal products being taken and consult health care professional before taking any new medications. Advise patient not to drink alcohol.

Evaluation/Desired Outcomes

● Decreased frequency and intensity of seizure activity.

Why was this drug prescribed for your patient?