Onfi (clobazam) - Drug Summary

Lundbeck Inc.

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Onfi
(clobazam)

THERAPEUTIC CLASS

Benzodiazepine

DEA CLASS

CIV

ADULT DOSAGE & INDICATIONS

Seizures

Associated w/ Lennox-Gastaut Syndrome:
≤30kg:
Initial: 5mg/day
Starting Day 7: 10mg/day
Starting Day 14: 20mg/day

>30kg:
Initial: 10mg/day
Starting Day 7: 20mg/day
Starting Day 14: 40mg/day

Do not proceed w/ dose escalation more rapidly than weekly

For doses >5mg/day, administer in divided doses bid

PEDIATRIC DOSAGE & INDICATIONS

Seizures

Associated w/ Lennox-Gastaut Syndrome:
≥2 Years:
≤30kg:
Initial: 5mg/day
Starting Day 7: 10mg/day
Starting Day 14: 20mg/day

>30kg:
Initial: 10mg/day
Starting Day 7: 20mg/day
Starting Day 14: 40mg/day

Do not proceed w/ dose escalation more rapidly than weekly

For doses >5mg/day, administer in divided doses bid

DOSING CONSIDERATIONS

Hepatic Impairment
Mild to Moderate (Child-Pugh Score 5-9):
Initial: 5mg/day
Titrate: Titrate according to weight, but to 1/2 the recommended dose, as tolerated; additional titration to the max dose (20mg/day or 40mg/day, depending on weight) may be started on day 21

Elderly
Initial: 5mg/day
Titrate: Titrate according to weight, but to 1/2 the recommended dose, as tolerated; additional titration to the max dose (20mg/day or 40mg/day, depending on weight) may be started on day 21

Discontinuation
Withdraw gradually; taper by decreasing total daily dose by 5-10mg/day on a weekly basis

Other Important Considerations
CYP2C19 Poor Metabolizers:
Initial: 5mg/day
Titrate: Titrate according to weight, but to 1/2 the recommended dose, as tolerated; additional titration to the max dose (20mg/day or 40mg/day, depending on weight) may be started on day 21

ADMINISTRATION

Oral route

Take w/ or w/o food

Tab
May administer whole, break in 1/2 along the score, or crush and mix in applesauce

Sus
Shake well before every administration
Administer using only the dosing syringe provided with the product
To Withdraw a Dose:
1. Insert the provided adapter firmly into the neck of the bottle before 1st use
2. Insert the dosing syringe into the adapter and invert bottle then slowly pull back plunger to prescribed dose
3. Remove the syringe from the bottle adapter and slowly squirt dose into the corner of the patient's mouth
4. Replace cap after each use (the cap fits over the adapter)

HOW SUPPLIED

Sus: 2.5mg/mL [120mL]; Tab: 10mg*, 20mg* *scored

CONTRAINDICATIONS

History of hypersensitivity to clobazam or its ingredients.

WARNINGS/PRECAUTIONS

Dose-related somnolence and sedation reported. May impair mental/physical abilities. Withdrawal symptoms reported to occur following abrupt discontinuation; withdraw gradually to minimize risk of precipitating seizures, seizure exacerbation, or status epilepticus. Serious skin reactions (eg, Stevens-Johnson syndrome [SJS], toxic epidermal necrolysis [TEN]) reported; d/c at the 1st sign of rash, unless the rash is clearly not drug-related. If signs/symptoms suggest SJS/TEN, do not resume therapy and consider alternative therapy. Monitor patients with history of substance abuse because of predisposition to habituation and dependence. May increase risk of suicidal thoughts or behavior; monitor for the emergence or worsening of depression, suicidal thoughts/behavior, and/or any unusual changes in mood/behavior.

ADVERSE REACTIONS

Somnolence, pyrexia, upper respiratory tract infection, lethargy, drooling, aggression, vomiting, irritability, constipation, fatigue, sedation, ataxia, insomnia, cough, pneumonia.

DRUG INTERACTIONS

May potentiate effects of other CNS depressants or alcohol; monitor for somnolence and sedation. May decrease effectiveness of hormonal contraceptives; additional nonhormonal forms of contraception are recommended. CYP2D6 substrates may require dose adjustment. Strong (eg, fluconazole, fluvoxamine, ticlopidine) and moderate (eg, omeprazole) inhibitors of CYP2C19 may increase exposure to N-desmethylclobazam; may require dose adjustment of clobazam. Alcohol may increase maximum plasma exposure.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Benzodiazepine; not established. Thought to involve potentiation of gamma-aminobutyric acid (GABA)ergic neurotransmission resulting from binding at the benzodiazepine site of the $GABA_A$ receptor.

PHARMACOKINETICS

Absorption: Rapid and extensive. T_{max}=0.5-4 hrs (tab, single- or multiple-dose), 0.5-2 hrs (sus, single-dose). **Distribution:** Plasma protein binding (80-90%; 70% N-desmethylclobazam); V_d=100L; found in breast milk. **Metabolism:** Liver (extensive); via N-demethylation by CYP3A4 (primary), 2C19, 2B6; N-desmethylclobazam (major, active metabolite). **Elimination:** Urine (82%, 2% unchanged), feces (11%, 1% unchanged); $T_{1/2}$=36-42 hrs, 71-82 hrs (N-desmethylclobazam).

ASSESSMENT

Assess for hypersensitivity to drug, hepatic impairment, history of substance abuse, pregnancy/nursing status, and possible drug interactions. Assess if patient is a CYP2C19 poor metabolizer.

MONITORING

Monitor for somnolence, sedation, withdrawal symptoms, habituation, physical/psychological dependence, emergence or worsening of depression, suicidal thoughts/behavior, unusual changes in mood/behavior, and other adverse reactions. Closely monitor for signs/symptoms of SJS/TEN, especially during the first 8 weeks of treatment initiation or when reintroducing therapy.

PATIENT COUNSELING

Caution about operating hazardous machinery, including automobiles, until the effect of the treatment is known. Inform to consult physician before increasing the dose or abruptly discontinuing the drug. Instruct to notify physician if a skin reaction occurs. Advise that abrupt withdrawal may increase risk of seizure. Counsel women to also use nonhormonal methods of contraception when clobazam is used with hormonal contraceptives and to continue these alternative methods for 28 days after discontinuation. Inform that clobazam may increase the risk of suicidal thoughts and behavior and counsel to be alert for the emergence or worsening of symptoms of depression, any unusual changes in mood/behavior, or the emergence of suicidal thoughts, behavior, or thoughts of self-harm; instruct to immediately report behaviors of concern to physician. Instruct to notify physician if pregnant/breastfeeding, or if intending to breastfeed or become pregnant during therapy. Encourage to enroll in the North American Antiepileptic Drug Pregnancy Registry if patient becomes pregnant.

STORAGE

20-25°C (68-77°F). (Sus) Store in original bottle in an upright position. Use within 90 days of 1st opening the bottle; discard any remainder.

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