Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Onfi™

Common Name: clobazam

PDL Category: Anticonvulsants

Comparable Products	Preferred Drug List Status
Banzel®	Non-Preferred
Felbatol®	Preferred
Lamotrigine	Preferred
Topiramate	Preferred

Summary

Indications and Usage: Indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in adults and children 2 years of age and older.[1]

Mechanism of Action: The exact mechanism of action for clobazam, a 1,5-benzodiazepine, is not fully understood but is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the $GABA_A$ receptor. [1]

Dosage Forms: Tablets: 5mg, 10mg, 20mg

Recommended Dosage: Patients ≤30 kg body weight: initiate therapy at 5 mg daily and titrate as tolerated up to 20 mg daily. Patients >30 kg body weight: initiate therapy at 10 mg daily and titrate as tolerated up to 40 mg daily. Doses above 5 mg/day should be administered in two divided doses. Dosage adjustment needed in the following groups: Geriatric patients, Known CYP2C19 poor metabolizers, Mild or moderate hepatic impairment; no information for severe hepatic impairment. [1]

Common Adverse Drug Reactions: Somnolence, sedation, drooling, constipation, cough, urinary tract infection, insomnia, aggression, fatigue, dysarthria.[1]

Contraindications: None

Manufacturer: Lundbeck Inc.

Analysis: Onfi™ is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in adults and children 2 years of age and older. The efficacy of Onfi™ as adjunctive therapy was established in two controlled studies. Study 1 was a randomized, double-blind, placebo-controlled study consisting of a 4 week baseline period, 3 week titration period, and 12 week maintenance period. The primary efficacy measure was the percent reduction in the weekly frequency of drop seizures from the 4 week baseline period to the 12 week maintenance period. Patients were stratified by weight and randomized to placebo or one of three target maintenance doses of Onfi™. All dose groups of Onfi™ were statistically superior to placebo in reducing seizure frequency. The effect appeared to be dose dependent. Study 2 was a randomized, double-blind comparison study of high and low dose Onfi™. A statistically significantly greater reduction in seizure frequency was observed in the high-dose group compared to the low-dose group, median percent reduction of 93% vs 29% respectively. Onfi™ is not intended as a first line treatment. It is recommended that Onfi™ be added to the Preferred Drug List as a non-preferred drug for confirmation of diagnosis and adjunctive treatment.

IME Recommendation:

- ☐ Preferred Drug
- ☒ Non-Preferred Drug
- ☐ Preferred Drug with Conditions
- ☐ Recommended Drug
- ☐ Non-Recommended Drug

1. Onfi™ [package insert]. Deerfield, IL: Lundbeck Inc.; 2011.