



Your Partner
in Epilepsy

FOR IMMEDIATE RELEASE

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ONFI™ (clobazam) Tablets Now Available in the U.S. at Retail Pharmacies

Deerfield, Ill. January 3, 2012 – Lundbeck announced today that ONFI Tablets are now available for prescribing in the United States. The FDA recently approved ONFI for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients two years and older.¹ ONFI is an oral anti-epileptic drug (AED) of the benzodiazepine class, and is a 1,5 benzodiazepine.¹ ONFI (pronounced “ON-fē”) is a federally controlled schedule four substance (C-IV).

“The availability of ONFI is the result of extensive efforts over many years by our team here at Lundbeck and the medical community,” said Staffan Schüberg, president of Lundbeck in the U.S. “We have been inspired by the courage of patients and families impacted by LGS, and their strength never to give up on the goal of additional seizure management. Recognizing the need for additional treatment options due to the intractable nature of this challenging seizure disorder, we are very pleased to make ONFI available in the U.S.”

LGS is a rare and severe form of epilepsy that is typically diagnosed in childhood and often persists into adulthood.^{2,3} LGS is associated with multiple types of seizures with periods of frequent seizures, and daily seizures are common.⁴ Some of these seizures, including atonic, tonic and myoclonic seizures, may cause falls, or “drop seizures” (also referred to as “drop attacks”), which may result in injury.²

“LGS can take a toll on even the strongest families due to the frequency and severity of seizures, including drop seizures.” said Yu-Tze Ng, director of epilepsy at the University of Oklahoma Medical School and lead investigator of clinical trials supporting the approval of ONFI. “In clinical trials, ONFI was shown to be an effective add-on therapy for seizures associated with LGS in adults and children two years and older. ONFI’s availability is important news for patients and their caregivers to discuss with physicians.”¹

Support to Help Patients Get Access to ONFI

ONFI is available to patients at retail pharmacies with a prescription from a healthcare professional. Additionally, if a healthcare professional elects, Lundbeck has created the ONFI Support Center that will assist healthcare professionals and patients with benefits investigation, prior authorizations and is responsible for Lundbeck’s patient assistance program. Where permissible, a sample voucher program will provide a free ONFI trial to any eligible patient. Also, co-pay assistance is being made available to those who are eligible. The ONFI Support Center is available by calling 855-345-6634.

About ONFI

ONFI is an oral antiepileptic drug developed in the United States by Lundbeck, and will be available in 5-mg, 10-mg, and 20-mg tablets. ONFI is a 1,5 benzodiazepine. The exact mechanism of action for ONFI 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

For more information, please visit www.ONFI.com.

Important Safety Information

- **ONFI can make you sleepy or dizzy and can slow your thinking and make you clumsy which may get better over time.** Do not drive, operate heavy machinery, or other dangerous activities until you know how ONFI affects you. Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking ONFI without first talking to your healthcare provider as your sleepiness or dizziness may get much worse.
- **ONFI can cause withdrawal symptoms.** Do not suddenly stop taking ONFI without first talking to a healthcare provider. Stopping ONFI suddenly can cause seizures that will not stop (status

epilepticus), hearing or seeing things that are not there (hallucinations), shaking, nervousness, and stomach and muscle cramps.

- **ONFI can be abused and cause dependence.** Physical dependence is not the same as drug addiction. Talk to your healthcare provider about the differences. **ONFI is a federally controlled substance (CIV) because it can be abused or lead to dependence.**
- **Like other antiepileptic drugs, ONFI may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.** Call your healthcare provider right away if you have any symptoms, especially sudden changes in mood, behaviors, thoughts, or feelings, and especially if they are new, worse, or worry you.
- Tell your healthcare provider about all of your medical conditions including liver or kidney problems, lung problems (respiratory disease), depression, mood problems, or suicidal thoughts or behavior.
- If you are pregnant or plan to become pregnant, ONFI may harm your unborn baby. You and your healthcare provider will have to decide if you should take ONFI while you are pregnant.
- ONFI can pass into breast milk. You and your healthcare provider should decide if you should take ONFI or breast feed. You should not do both.
- Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements as taking ONFI with certain other medicines can cause side effects or affect how well they work. ONFI may make your birth control medicine less effective. Talk to your healthcare provider about the best method to use.
- The most common side effects seen in ONFI patients include: sleepiness; drooling; constipation; cough; pain with urination; fever; acting aggressive, being angry or violent; difficulty sleeping; slurred speech; tiredness; and problems with breathing.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For more information, please see the [ONFI Medication Guide](#) and [full Prescribing Information](#).

ONFI is a trademark of Lundbeck.

About Lundbeck in the U.S.

A wholly owned subsidiary of H. Lundbeck A/S of Denmark, Lundbeck in the United States is headquartered in Deerfield, Illinois, and is committed to providing innovative specialty therapies that fulfill unmet medical needs of people with central nervous system (CNS) disorders, including challenging seizure disorders.

With a special commitment to addressing the needs of the epilepsy community, Lundbeck makes several therapies available in the United States for people with difficult-to-treat seizure disorders. Each year, Lundbeck employees actively support and participate in community-based initiatives, including more than 100 epilepsy awareness events, as part of an ongoing commitment to make a difference for those impacted by epilepsy.

For more information, please visit www.lundbeckus.com.

About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUKY) is an international pharmaceutical company highly committed to improving the quality of life for people suffering from brain disorders. For this purpose, Lundbeck is engaged in the research, development, production, marketing and sale of pharmaceuticals across the world. The company's products are targeted at disorders such as depression and anxiety, schizophrenia, insomnia, epilepsy, and Huntington's, Alzheimer's and Parkinson's diseases.

Lundbeck was founded in 1915 by Hans Lundbeck in Copenhagen, Denmark. Today Lundbeck employs approximately 5,900 people worldwide. Lundbeck is one of the world's leading pharmaceutical companies working with brain disorders. In 2010, the company's revenue was DKK 14.8 billion (approximately EUR 2.0 billion or USD 2.6 billion). For more information, please visit www.lundbeck.com.

Sources

1. ONFI Full [Prescribing Information](#). Deerfield, IL: Lundbeck. October 2011.
2. Van Rijckevorsel, Kenou et al. Treatment of Lennox-Gastaut syndrome: overview and recent findings. *Neuropsychiatric Disease and Treatment*. 2008; 4(6) 1001-1019.
3. Glauser, Tracey. Lennox-Gastaut Syndrome. Medscape. 2011.
<http://emedicine.medscape.com/article/1176735-overview>. Last accessed 9/23/11.
4. Borggraefe I, Noachtar S. Pharmacotherapy of Seizures Associated with Lennox-Gastaut Syndrome. *Clinical Medicine Insights: Therapeutics*. 2010;2 15-24.