ONFI® (clobazam) CIV Scored Tablets and Oral Suspension Now Available in U.S. Pharmacies

New Formulations Provide Dosing Flexibility for Physicians and their Patients
ONFI.com Updated with New Tools and Resources for Families

Deerfield, Ill. August 12, 2013 – Lundbeck announced today that ONFI (clobazam) CIV will be available in scored tablet and oral suspension formulations beginning this week. These new formulations were recently approved by the U.S. Food & Drug Administration (FDA). ONFI is a prescription medication originally approved by the FDA in 2011, and is used along with other medicines to treat seizures associated with Lennox-Gastaut syndrome (LGS) in adults and children 2 years of age or older. ONFI is an oral anti-epileptic drug (AED) of the benzodiazepine class, and is a 1,5 benzodiazepine. It is a federally controlled schedule four substance (CIV).

The new oval shaped ONFI Scored Tablets (10 mg and 20 mg) will replace the previously available round non-scored tablets, and are similar in size. These new tablets contain the same ingredients as the round tablet, and include a functional score to allow patients or their caregivers to split the tablets in half. ONFI will no longer be available in a 5 mg tablet. ONFI Oral Suspension (2.5 mg/mL) has a berry flavor, and provides an alternative to ONFI Tablets.

“Since becoming available nearly two years ago, ONFI has become an important additional treatment option for people with LGS,” said Raman Sankar, MD, PhD, Professor of Neurology and Pediatrics and Chief of Pediatric Neurology at the David Geffen School of Medicine at the University of California, Los Angeles. “ONFI Scored Tablets and Oral Suspension provide flexibility when making dose adjustments. Also, it’s very helpful to have medications available in both tablet and oral suspension formulations to provide options for patients and their caregivers.”

LGS is a rare and severe form of epilepsy that is typically diagnosed in childhood and often persists into adulthood. LGS is associated with multiple types of seizures with periods of frequent seizures, and daily seizures are common. 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.

“The availability of these new formulations are the result of working closely with the LGS community and listening to the needs of physicians, patients and those who care for them,” said Mike Hanley, Director of ONFI Marketing, Lundbeck US. “We are inspired by the strength of those impacted by LGS and will continue working together to help these patients and their families.”

ONFI.com Updated with New Tools and Resources for Families
Helpful resources for patients and their families, including an animated video guide to the new formulations, are available at ONFI.com. The website also features new content to support families, including videos from parents of children and adults with LGS discussing their experience with LGS and ONFI, as well as downloadable tools.

Jackie, whose daughter has LGS, is one of several parents who shares her experience in a video on ONFI.com. “LGS affects such a wide range of people, and there really are no two people with LGS that are exactly alike. That in itself is motivation to keep trying new things,” said Jackie. “Several years back, my husband and I weighed the benefits and the risks and ultimately decided that we would try ONFI for our daughter, and we’re thankful that we did.”

Please visit ONFI.com to learn more.
About ONFI® (clobazam) CIV

ONFI is an oral antiepileptic drug developed in the United States by Lundbeck, and is now available in 10-mg and 20-mg tablets, and as a 2.5 mg/mL Oral Suspension. 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.\(^1\) More than 150,000 prescriptions of ONFI have been written in the United States.

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 do 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. ONFI may make your sleepiness or dizziness 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.**

- **Serious skin reactions have been seen when ONFI is taken with other medicines and may require stopping its use.** A serious skin reaction can happen at any time during your treatment with ONFI. Call your healthcare provider immediately if you have skin blisters, peeling rash, sores in the mouth, hives or any other allergic reaction.

- **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.

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

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

ONFI is a registered 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 several therapies for people with challenging seizure disorders.

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With a special commitment to the epilepsy community, Lundbeck makes a scholarship available that's helped 39 people attend the LGS Foundation’s Family & Professional Conference. Each year our employees actively support and participate in hundreds of community-based initiatives, including Studio E, an art therapy program Lundbeck makes available with the Epilepsy Foundation. Learn more about our epilepsy community programs at YourPartnerInEpilepsy.com.

About Lundbeck
Lundbeck is a global pharmaceutical company highly committed to improving the quality of life of people living with brain diseases. For this purpose, Lundbeck is engaged in the entire value chain throughout research, development, production, marketing and sales of pharmaceuticals across the world. The company's products are targeted at disorders such as depression and anxiety, psychotic disorders, epilepsy, Huntington's, Alzheimer's and Parkinson's diseases. Lundbeck's pipeline consists of several mid- to late-stage development programs.

Lundbeck employs more than 5,800 people worldwide, 2,000 of whom are based in Denmark. We have employees in 57 countries and our products are registered in more than 100 countries. We have research centers in Denmark, China and the United States and production facilities in Italy, France, Mexico, China and Denmark. Lundbeck generated revenue of approximately DKK 15 billion in 2012. Lundbeck’s shares are listed on the stock exchange in Copenhagen under the symbol "LUN." Lundbeck has a sponsored Level 1 ADR programme listed in the US (OTC) under the symbol "HLUYY." For additional information, we encourage you to visit our corporate site www.lundbeck.com.

Sources

1. ONFI Full Prescribing Information. Deerfield, IL: Lundbeck.


