



**For Immediate Release**

**MEDA INTRODUCES EDLUAR™, THE FIRST AND ONLY SUBLINGUAL TABLET THAT CONTAINS THE MOST PRESCRIBED SLEEP MEDICATION, ZOLPIDEM TARTRATE**

**Somerset, NJ, September 8, 2009** — Meda Pharmaceuticals Inc. (Meda) today announced the commercial availability of EDLUAR™ (zolpidem tartrate sublingual tablets) in the United States. EDLUAR is indicated for the short-term treatment of insomnia characterized by difficulties with falling asleep. EDLUAR is the first available under-the-tongue formulation of zolpidem tartrate, which is the most prescribed treatment for insomnia. Zolpidem tartrate is also the active ingredient in Ambien® oral tablets.

“Insomnia is a serious and common medical problem that affects tens of millions of Americans,” said Sharon S. Clarke, president and general manager of Meda. “With the introduction of EDLUAR sublingual tablets, patients with insomnia who have trouble falling asleep now have another treatment option. We are pleased to be the company that brings this innovative new formulation to these patients.”

According to a “Sleep in America” poll conducted by the National Sleep Foundation, one in five people surveyed reported difficulty falling asleep at least a few nights a week.<sup>1</sup>

“Insomnia is a complex problem because patients can present with a variety of troubling symptoms,” said Harry Sacks, M.D., vice president, medical affairs of Meda. “EDLUAR combines the efficacy and safety profile of zolpidem tartrate – an agent used for 17 years – with a new sublingual formulation that is convenient for patients with short-term insomnia whose primary complaint is the inability to fall asleep.”

EDLUAR sublingual tablets contain the active ingredient zolpidem tartrate and have a pharmacokinetic profile characterized by rapid absorption. EDLUAR offers simple and convenient administration. Patients should follow these instructions when taking EDLUAR: Take EDLUAR right before getting into bed. Place the tablet under the tongue, where it will disintegrate. It should not be swallowed or taken with water, alcohol or any other liquid. Do not take EDLUAR unless you are able to stay in bed a full night (7 to 8 hours) before you must be active again. EDLUAR should not be taken with a meal or immediately after a meal.

## **EDLUAR Instant Savings Program Now Available**

Insured patients may be eligible for savings on co-payments for prescriptions of EDLUAR sublingual tablets. For eligible patients, Meda will cover 100% of the first co-pay for a prescription of EDLUAR sublingual tablets. Patients will pay their plans' co-pay amounts, up to \$20, for four additional fills of EDLUAR sublingual tablets; the balance, if any, is covered by the EDLUAR Instant Savings Program. For more information including eligibility, exclusions and further details, please visit [www.edluar.com](http://www.edluar.com).

## **About EDLUAR**

EDLUAR sublingual tablets received marketing approval from the U.S. Food and Drug Administration (FDA) on March 13, 2009 for the short-term treatment of insomnia characterized by difficulties with sleep initiation. EDLUAR sublingual tablets are available in 5-mg and 10-mg strengths, and the once-daily adult dose should not exceed 10 mg. In the elderly/debilitated or hepatic impaired patients, the once-daily dose should not exceed 5 mg. For more information about EDLUAR sublingual tablets, including full prescribing information and medication guide, please visit [www.edluar.com](http://www.edluar.com).

## **Important Safety Information**

Allergic reactions such as sudden trouble breathing, swelling of your tongue or throat may occur and in rare cases may be fatal. If you are allergic to zolpidem tartrate or any of EDLUAR's inactive ingredients, don't take this product. If you have an allergic reaction while using EDLUAR, do not take another dose and contact your doctor immediately.

Sleepwalking, eating, driving or doing other activities while not fully awake, with memory loss for the event, as well as abnormal behaviors such as being more outgoing or aggressive than normal, confusion, agitation, and hallucinations may occur. Using EDLUAR with alcohol or other medicines that can make you sleepy can increase the risk of these behaviors. EDLUAR can impair your alertness and motor coordination. After taking EDLUAR, don't drive or operate machinery until you are fully awake. Don't take EDLUAR with alcohol.

In patients with depression, worsening of depression (including suicidal thoughts, actions and completed suicides) may occur. If your depression worsens, contact your doctor immediately.

The most commonly observed side effects in controlled clinical trials were next-day drowsiness, dizziness, headache, diarrhea and drugged feelings.

Because EDLUAR works quickly, you should take EDLUAR immediately before going to bed.

When taking EDLUAR, stay in bed for a full night (7 to 8 hours) before you must be active again. EDLUAR can be taken for 7 to 10 days or as advised by your doctor. If your sleep problems continue, consult your doctor, who will determine whether another condition is

causing your sleep problem or other measures are needed to overcome your sleep problems.

EDLUAR is a federally controlled substance and can be abused or lead to dependence. After you stop taking EDLUAR, you may have symptoms for 1 to 2 days, such as trouble sleeping, nausea and vomiting, flushing, lightheadedness, and nervousness.

You are encouraged to report side effects of prescription drugs to the Food and Drug Administration (FDA). Please visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088 or contact Meda Pharmaceuticals Inc. at 1-800-526-3840.

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**MEDA AB (publ)** is a leading international specialty pharma company. Meda's products are sold in 120 countries worldwide and the company is represented by its own organizations in more than 40 countries. The Meda share is listed under Large Cap on the Nasdaq OMX Nordic Stock Exchange in Stockholm. Find out more, visit [www.meda.se](http://www.meda.se).

Ambien<sup>®</sup> is a registered trademark of sanofi-aventis US LLC.

1. National Sleep Foundation 2005 "Sleep in America" Poll