Initial REMS Approval: December 2008
Most Recent REMS Modification: October 2010.

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

NDA 22196 Zolpimist (zolpidem tartrate) oral spray

Sedative / Hypnotic
Imidazopyridine Class
NovaDel Pharma, Inc.
25 Minneakoning Rd. Suite 101
Flemington, NJ 08822

I. GOAL(S)

The goal of the REMS is to effectively communicate to patients the risks involved with Zolpimist® (zolpidem tartrate), 5 mg and 10 mg oral spray (Zolpimist), and how to use Zolpimist safely.

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide and Patient Instructions for Use will be dispensed with each Zolpimist prescription. Zolpimist is packaged as a single unit of use. The primary packaging of Zolpimist is a spray bottle that has a carton as the secondary packaging. The Zolpimist Medication Guide and Patient Instructions for Use are bar-coded to ensure the correct version is being used and then inserted into each carton. The carton, containing the Medication Guide and Patient Instructions for Use, will be provided directly to the patient at the time the prescription is dispensed by the pharmacy and requires no repackaging by the pharmacy. Thus, patients will automatically receive the Zolpimist Medication Guide and Patient Instructions for Use with their prescription.

B. Communication Plan

The REMS for Zolpimist does not include a Communication Plan.

C. Elements to Assure Safe Use

The REMS for Zolpimist does not include elements to assure safe use.

D. Implementation System

Because this REMS for Zolpimist does not include elements to assure safe use, an implementation system is not required.

E. Timetable for Submission of Assessments

NovaDel Pharma Inc. (NovaDel) will submit REMS assessments to FDA 18 months, 3 years, 4 years, and 7 years from the date of initial approval of the REMS (December 19, 2008) according to the following schedule: First FDAAA assessment on June 19, 2010 (18 months from approval), second FDAAA assessment on December 19, 2011 (3 years from approval), third FDAAA assessment on December 19, 2012 (4 years from approval), and fourth FDAAA assessment on December 19, 2015 (7 years from approval). NovaDel will submit each assessment so that it will be received by FDA on or before the due date.