

# AU InforMed

Volume 13 Number 2 (Issue 275)

Monday, March 2, 2015

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## Key Inforbits

- Healthy Sleep Tips
- National Sleep Awareness Week 2015
- Common Sleep Disorders
- Recently FDA Approved Drugs

## 10 Tips for Healthy Sleep

### Keep a schedule

- Having a consistent bedtime and wake up time will help regulate your body's clock and could help you fall asleep and stay asleep for the night.

### Relax

- A relaxing, routine activity before bedtime in dim lighting can help separate your daily activities from bedtime.

### Avoid Naps

- Napping, especially in the afternoons may get you through the day, but can cause difficulty falling asleep at bedtime.

### Exercise

- Even mild exercise will help you rest easier, but don't exercise at the expense of your sleep.

### Have a Good Sleep Environment

- The bedroom should be cool, comfortable, and free from disturbing noises and distractions.

### Sleep on Comfortable Mattress and Pillows

- Comfortable pillows make the room inviting for sleep, but a good quality mattress is also a must-have for good sleep. (Mattresses lose their support and comfort after 9-10 years)

### Use Bright Light

- By avoiding bright light in the evenings and exposing yourself to it in the mornings will help manage your circadian rhythms.

### Watch What You Eat and Drink

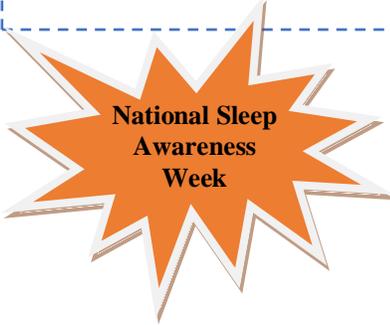
- Alcohol, cigarettes, caffeine, and heavy meals in the evening can make it hard to sleep.

### Wind Down

- Calming activities, such as reading, the last hour before bed can help shift your body into sleep mode.

### The Bed is for Sleeping

- It is best to take work materials, computers, and televisions out of the sleeping environment.<sup>1</sup>



National Sleep  
Awareness  
Week

Every year the National Sleep Foundation hosts a sleep awareness week campaign to celebrate the health benefits of sleep. This year March 2<sup>nd</sup>-8<sup>th</sup> has been designated as sleep awareness week. This week starts with the release of this year's Sleep in America poll, and ends with Daylight Savings Time. For more information about the campaign, visit: [www.sleepfoundation.org](http://www.sleepfoundation.org).<sup>2</sup>



## **Common Sleep Disorders**

**Normal Sleep:** Sleeping occurs in stages, initially, a light stage of sleep, then progression occurs into an increasingly deeper sleep. Following about 90 minutes, the first stage of Rapid Eye Movement (REM) sleep (dreaming) is entered. During the night sleep cycles alternate REM and non-REM sleep.<sup>3</sup>

**Narcolepsy:** A neurological disorder affecting the regulation of the normal sleep-wake cycles. It affects both men and women equally and develops with age. A combination of both genetics and environmental factors can contribute to this condition. Narcolepsy is associated with sleep attacks, dream-like hallucinations, insomnia, and sleep paralysis. Those with narcolepsy typically begin with REM sleep and these fragments can occur involuntarily throughout the waking hours. During REM sleep the muscles of the body undergo paralysis causing dramatically debilitating symptoms when occurring during the day. Typically those with narcolepsy sleep a normal amount, but they cannot control the timing of their sleep. There is no cure for narcolepsy but treatments include both medication and behavioral therapy. Medical treatment includes, stimulants, antidepressants, and sodium oxybate given at night, with the goal of therapy being able to achieve normal alertness with minimal side effects.<sup>3</sup>

**Insomnia:** The difficulty falling asleep or staying asleep, even when able to do so. Insomnia can be characterized as acute or chronic. Acute insomnia is often associated with life circumstances, and typically does not need treatment. Chronic insomnia may occur at least 3 nights a week and lasts for at least 3 months, caused by many different factors. Treatment options include behavioral, psychological, medical or a combination. Examples of prescription medical treatment are benzodiazepine hypnotics, non-benzodiazepine hypnotics, and melatonin.<sup>4</sup>

**Sleep Apnea:** Sleep apnea can be obstructive or central. Obstructive is the most common type of sleep apnea, accounting for 80% or more of sleep apnea cases. Central sleep apnea typically occurs in those with central nervous system (CNS) dysfunction, whereas obstructive is caused by blockage of the airway from the soft tissue in the rear of the throat. In obstructive sleep apnea breathing is paused sometimes up to 10 seconds leading to fragmented sleep and low blood oxygen levels. Sleep apnea can lead to hypertension, heart disease and mood and memory problems. Treatment choices include continuous positive airway pressure device (CPAP), dental appliances, weight loss, avoidance of alcohol, smoking cessation, and sleeping position. Treatment for central sleep apnea include, CPAP, BIPAP (Bilevel positive airway pressure), oxygen, and treatment of underlying CNS disorders.<sup>5</sup>

**Restless Leg Syndrome (RLS):** A neurological sensorimotor disorder causing an overwhelming urge to move ones legs when at rest, sometimes accompanied with an unpleasant sensation. RLS is classified as either primary or secondary. Primary RLS is the most common and can be hereditary or idiopathic. Secondary RLS is associated with an underlying medical condition, use of certain drugs or environmental factors. Such conditions include vein disease, kidney failure, pregnancy, stress and diet. Medication that can cause RLS are TCAs, SSRIs and SNRIs. The severity of RLS may increase with age, with more frequent symptoms and for longer periods of time. Treatment includes, dopaminergic agents, benzodiazepines, opioids, anticonvulsants, and lifestyle changes.<sup>6</sup>

# **Recently FDA-Approved Sleep Drugs**

**Hetlioz (Tasimelteon):** On Jan. 31, 2015, the FDA approved Hetlioz (tasimelteon) as the first and only treatment for Non-24-Hour Sleep-Wake Disorder (Non-24). Non-24 disrupts circadian rhythms and may create periods of nighttime sleep disruption and daytime sleepiness in patients who are totally blind. Tasimelteon is an agonist of melatonin MT1 and MT2 receptors; these receptors are thought to be involved in the control of circadian rhythms. Hetlioz is available in 20 mg strength capsules for oral administration costing approximately \$8,420 for a 30 day supply. The recommended dosage of Hetlioz is 20 mg per day orally taken before bedtime, at the same time every night. Absorption is delayed with high-fat meals therefore tasimelteon should be taken without food. Drug effect may take weeks or months due to individual differences in circadian rhythms.<sup>8-11</sup>

Use is not recommended in severe hepatic impairment (Child-Pugh class C). Use has not been studied in pediatric patients (<18 years old) and caution is warranted in elderly patients (≥ 65 years old). Tasimelteon has not been studied in pregnancy and should only be used if the potential benefit justifies the potential risks.<sup>8-11</sup>

Tasimelteon is extensively metabolized primarily via CYP1A2 and CYP3A4 isozymes. It should not be taken with fluvoxamine or rifampin. Strong CYP1A2 inhibitors (such as fluvoxamine) may cause a potentially large increase in tasimelteon exposure and greater risk of adverse reactions. Smoking causes induction of CYP1A2 levels and therefore efficacy of tasimelteon may be reduced in smokers. Strong CYP3A4 inducers (like rifampin) may cause a potentially large decrease in tasimelteon exposure with reduced efficacy.<sup>8-11</sup>

Tasimelteon may cause drowsiness, headache, elevated liver enzymes (ALT), nightmares or abnormal dreams, and upper respiratory or urinary tract infection. Side effects may occur more commonly in elderly patients due to an approximately 2-fold increase in exposure compared to younger adults.<sup>8-11</sup>

**Belsomra (Suvorexant):** The FDA has recently (Aug 13, 2014) approved Belsomra (suvorexant) a class IV controlled substance for the treatment of insomnia characterized with difficulties with sleep onset and/or maintenance. Suvorexant has been studied for up to 3 months in two randomized, double-blind clinical trials. Belsomra is available in 5, 10, 15 and 20 mg strength tablets for oral administration costing approximately \$315 for a 30 day supply. Suvorexant blocks the binding of orexin A and orexin B (wake-promoting neuropeptides) to receptors OX1R and OX2R, which is thought to suppress wake drive. The FDA-approved dose for insomnia is Belsomra 10 mg once daily within 30 minutes of bedtime. It may be increased to the maximum daily dose of 20 mg if the 10 mg dose is well-tolerated but not effective. Onset is approximately 30 minutes and is delayed with food, therefore, suvorexant should not be administered with or immediately after a meal. AUC and C<sub>max</sub> levels are increased in obese versus non-obese patients and in women versus men. Suvorexant is contraindicated in narcolepsy due to the potential for orexin receptor antagonism to cause narcoleptic symptoms.<sup>8-11</sup>

Suvorexant is primarily metabolized by CYP450 3A. Concomitant therapy is not recommended with strong CYP450 3A inhibitors and the dose should be reduced to 5 mg (not to exceed 10

mg) with moderate CYP450 3A inhibitors. Dosage adjustments of suvorexant and/or other CNS depressants may be necessary in concomitant therapy.<sup>8-11</sup>

Suvorexant may cause daytime sleepiness, unclear thinking, memory loss, temporary sleep paralysis, sleep-walking or abnormal thoughts and behavior.<sup>8-11</sup>

## **How Much Sleep Do We Need??**<sup>7</sup>

<b>AGE</b>	<b>RECOMMENDED AMOUNT OF SLEEP</b>
Newborns	16-18 hours a day
Preschool-aged children	11-12 hours a day
School-aged children	At least 10 hours a day
Teens	9-10 hours a day
Adults (including elderly)	7-8 hours a day

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### The Last Dose

**“The only words I understand in the morning are ‘go back to sleep’ and ‘bacon’.”** ~Anonymous

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