

**Brand Name:** Belsomra

**Generic:** suvorexant

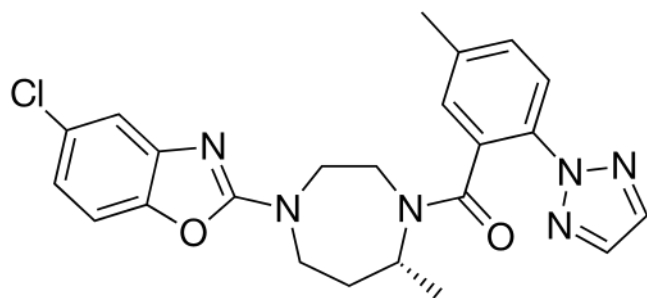
**Type:** small molecule

**Year Accepted/Phase:** 2014

### **Mechanism:**

Suvorexant is an orexin receptor antagonist. Orexins are neuropeptides produced in the hypothalamus that play a key role in regulating the sleep-wake cycle. They promote wakefulness by activating orexin receptors (OX1R and OX2R). Suvorexant works by selectively blocking these orexin receptors, thereby inhibiting the wake-promoting activity of orexin, facilitating the transition to sleep and maintaining sleep throughout the night.

### **Chemical Structure:**



### **Indication:**

Belsomra is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance in adults.

## Clinical trials:

### Phase II Trial

**Purpose:** Evaluate the efficacy and safety of suvorexant in patients with primary insomnia.

**Dates:** Conducted from 2008 to 2010.

**Results:** The trial demonstrated that suvorexant significantly improved both sleep onset and sleep maintenance compared to placebo. The medication was well tolerated, with the most common side effects being somnolence and fatigue.

**Impact:** These results supported further investigation into the efficacy and safety of suvorexant in larger, longer-term studies.

### Phase III Trial (SUNRISE 1)

**Purpose:** Assess the efficacy of suvorexant in improving sleep onset and maintenance over a one-month period in patients with primary insomnia.

**Dates:** Conducted from 2010 to 2013.

**Results:** The study found that suvorexant significantly reduced the time to sleep onset and increased total sleep time compared to placebo. Improvements were seen as early as the first night of treatment and were maintained throughout the study.

**Impact:** The positive results from this trial were instrumental in demonstrating the efficacy of suvorexant and contributed to its FDA approval.

### Phase III Trial (SUNRISE 2)

**Purpose:** Evaluate the long-term efficacy and safety of suvorexant in patients with primary insomnia over a one-year period.

**Dates:** Conducted from 2010 to 2014.

**Results:** The trial showed that suvorexant maintained its efficacy in improving sleep onset and maintenance over one year. The medication was generally well tolerated, with no new safety concerns emerging over the extended treatment period.

**Impact:** These findings provided strong evidence for the long-term safety and efficacy of suvorexant, supporting its use for chronic insomnia.