

LUNESTA (compared to sugar pill) to reduce current symptoms for adults with insomnia

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| What is this drug for? | To make it easier to fall or to stay asleep |
| Who might consider taking it? | Adults age 18 and older with insomnia for at least 1 month |
| Recommended monitoring | No blood tests, watch out for abnormal behavior |
| Other things to consider doing | Reduce caffeine intake (especially at night), increase exercise, establish regular bedtime, avoid daytime naps |

LUNESTA STUDY FINDINGS

788 healthy adults with insomnia for at least 1 month -- sleeping less than 6.5 hours per night and/or taking more than 30 minutes to fall asleep-- were given LUNESTA or a sugar pill nightly for 6 months. Here's what happened:

| What difference did LUNESTA make? | People given a sugar pill | People given LUNESTA (3 mg each night) |
|--|---------------------------|--|
| Did LUNESTA help? | | |
| LUNESTA users fell asleep faster (15 minutes faster due to drug) | 45 minutes to fall asleep | 30 minutes to fall asleep |
| LUNESTA users slept longer (37 minutes longer due to drug) | 5 hours 45 minutes | 6 hours 22 minutes |
| Did LUNESTA have side effects? | | |
| <i>Life threatening side effects</i> No difference between LUNESTA and a sugar pill | None observed | |
| <i>Symptom side effects</i> | | |
| More had unpleasant taste in their mouth (additional 20% due to drug) | 6% 6 in 100 | 26% 26 in 100 |
| More had dizziness (additional 7% due to drug) | 3% 3 in 100 | 10% 10 in 100 |
| More had drowsiness (additional 6% due to drug) | 3% 3 in 100 | 9% 9 in 100 |
| More had dry mouth (additional 5% due to drug) | 2% 2 in 100 | 7% 7 in 100 |
| More had nausea (additional 5% due to drug) | 6% 6 in 100 | 11% 11 in 100 |

How long has the drug been in use?

Lunesta was approved by FDA in 2005. As with all new drugs we simply don't know how its safety record will hold up over time. In general, if there are unforeseen, serious drug side effects, they emerge after the drug is on the market (when a large enough number of people have used the drug).