

# media fact sheet

## NUVIGIL® (ARMODAFINIL) TABLETS [C-IV]

---

<b>What is NUVIGIL?</b>	NUVIGIL® (armodafinil) Tablets [C-IV] is a wakefulness-promoting agent. Armodafinil is the longer-lasting isomer of modafinil. NUVIGIL is approved by the U.S. Food and Drug Administration (FDA) to improve wakefulness in patients with excessive sleepiness associated with shift work disorder (SWD), treated obstructive sleep apnea (OSA), or narcolepsy. In patients with OSA, NUVIGIL is used along with other medical treatments for this condition.
<b>How does NUVIGIL work?</b>	NUVIGIL is a wake-promoting agent that is structurally distinct from amphetamines. Although its exact mechanism of action is not known, it is believed to work selectively through the sleep/wake centers of the brain to activate the cerebral cortex, which is essential for wakefulness. NUVIGIL promotes wakefulness without causing generalized stimulation of the brain.
<b>How has the effectiveness of NUVIGIL been demonstrated?</b>	NUVIGIL was studied in four 12-week, double-blind, placebo-controlled Phase III studies of over 1,100 patients and provided statistically significant improvements in wakefulness in those with excessive sleepiness associated with SWD, treated OSA, and narcolepsy.  Primary endpoints in all studies were measures of objective sleep latency. This included Maintenance of Wakefulness Test or Multiple Sleep Latency Test (standard objective sleep laboratory measurements), as well as Clinical Global Impression of Change (a physician rating of overall disease severity).
<b>How does NUVIGIL affect sleep?</b>	In clinical trials, NUVIGIL did not adversely affect sleep as measured by polysomnography, although five percent of patients reported insomnia.
<b>What are the recommended doses of NUVIGIL?</b>	The recommended dose of NUVIGIL for patients with treated OSA and narcolepsy is 150 mg or 250 mg given as a single dose in the morning. In patients with OSA doses up to 250 mg/day, given as a single dose, have been well-tolerated, but there is no consistent evidence that this dose confers additional benefit beyond that of the 150 mg/day dose. The recommended dose of NUVIGIL for patients with SWD is 150 mg given daily approximately one hour prior to the start of the individual's work shift.
<b>Does NUVIGIL have the potential for abuse?</b>	NUVIGIL is a federally controlled substance (C-IV) because it can be abused or lead to dependence. NUVIGIL should be kept in a safe place to prevent misuse and abuse. Selling or giving away NUVIGIL may harm others, and is against the law. Patients should tell their doctor if they have ever abused or been dependent on alcohol, prescription medicines or street drugs.

**What important information should patients know about NUVIGIL?**

**What is NUVIGIL?**

NUVIGIL is a prescription medicine used to improve wakefulness in adults who experience excessive sleepiness (ES) due to one of the following diagnosed sleep disorders: obstructive sleep apnea (OSA), shift work disorder (SWD), or narcolepsy.

In patients with OSA, NUVIGIL is used along with other medical treatments for this sleep disorder. NUVIGIL is not a replacement for your current OSA treatment, and it is important that you continue to use this treatment as prescribed by your doctor.

NUVIGIL may help the sleepiness caused by these conditions, but it may not stop all of your sleepiness and does not take the place of sleep.

NUVIGIL is a federally controlled substance (C-IV), so use NUVIGIL only as directed and keep in a safe place to prevent misuse and abuse. It is against the law to sell or give NUVIGIL to another person.

#### What important information should I know about NUVIGIL?

- NUVIGIL may cause serious side effects including a serious rash or a serious allergic reaction that may affect parts of your body such as your liver or blood cells, and may result in hospitalization and be life-threatening. If you develop a skin rash, hives, sores in your mouth, blisters, swelling, peeling, or yellowing of the skin or eyes, trouble swallowing or breathing, dark urine, or fever, stop taking NUVIGIL and call your doctor right away or get emergency help.
- NUVIGIL is not approved for children for any condition. It is not known if NUVIGIL is safe or if it works in children under the age of 17.
- You should not take NUVIGIL if you have had a rash or allergic reaction to NUVIGIL or PROVIGIL® (modafinil) Tablets [C-IV], or are allergic to any of the following ingredients: modafinil, armodafinil, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, or pregelatinized starch.

#### What are possible side effects of NUVIGIL?

- Stop taking NUVIGIL and call your doctor or get emergency help if you get any of the following serious side effects:
  - Mental (psychiatric) symptoms, including: depression, feeling anxious, sensing things that are not really there, increase in activity (mania), thoughts of suicide, aggression, or other mental problems
  - Symptoms of a heart problem, including: chest pain, abnormal heart beat, and trouble breathing
- Common side effects of NUVIGIL are headache, nausea, dizziness, and trouble sleeping. These are not all the side effects of NUVIGIL.
- Tell your doctor if you get any side effect that bothers you or that does not go away. Talk to your doctor for medical advice about side effects.

#### What should I avoid while taking NUVIGIL?

- Do not drive a car or do other dangerous activities until you and your doctor know how NUVIGIL affects you.
- Avoid drinking alcohol.

#### What should I tell my doctor before starting NUVIGIL?

- Tell your doctor about all of your health conditions including if you have: history of mental health problems (including psychosis), heart problems or had a heart attack, high blood pressure, liver or kidney problems, a history of drug or alcohol abuse or addiction, or are pregnant, planning to become pregnant, or breastfeeding.
- Tell your doctor about all of the medicines you take. Women who use hormonal birth control may have a higher chance of getting pregnant, while taking and for one month after stopping NUVIGIL. Talk to your doctor about other birth control methods while taking NUVIGIL.

You are encouraged to report side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), call 1-800-FDA-1088, or by fax at 1-800-FDA-0178.

It is important to know that NUVIGIL has historically been known to have an odor characteristic of the active ingredient. This odor is normal and there is no evidence to suggest that this odor affects the safety or efficacy of the product. Patients can continue taking their medication as prescribed and should refer concerns to their healthcare professional.

For more information, ask your doctor or call 1-800-896-5855, or go to [www.NUVIGIL.com](http://www.NUVIGIL.com).

This information does not take the place of talking with your doctor for medical advice about your condition or treatment.

**Please read the Medication Guide for Patients in the full prescribing information for NUVIGIL.**

How long has NUVIGIL been available?

NUVIGIL became commercially available in the United States in June 2009.



**What does the  
investigational clinical  
development program  
for armodafinil look like?**

Cephalon is studying armodafinil as adjunct therapy for depression associated with bipolar I disorder.

**Who makes NUVIGIL?**

Cephalon Inc. (Nasdaq: CEPH), Frazer, PA, an international biopharmaceutical company, holds exclusive rights to market and develop NUVIGIL in the United States.

Through the CephalonCares<sup>SM</sup> Foundation, Cephalon helps patients who do not have prescription drug coverage get the Cephalon medicine they need. For more information about Cephalon or the CephalonCares Foundation, visit [www.cephalon.com](http://www.cephalon.com).

**Full prescribing information** about NUVIGIL is available from Cephalon Medical Services (800-896-5855) or at [www.NUVIGIL.com](http://www.NUVIGIL.com)

###

