

# media fact sheet

## PROVIGIL® (MODAFINIL) TABLETS [C-IV]

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<b>What is PROVIGIL?</b>	PROVIGIL® (modafinil) tablets [C-IV] is a wakefulness-promoting agent. Modafinil is a racemic mixture (equal parts) of a longer-lasting R isomer and a shorter-lasting S isomer. PROVIGIL 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, PROVIGIL is used along with other medical treatments for this condition.
<b>How does PROVIGIL work?</b>	PROVIGIL 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. PROVIGIL promotes wakefulness without causing generalized stimulation of the brain.
<b>How has the effectiveness of PROVIGIL been demonstrated?</b>	<p>PROVIGIL was studied in five placebo-controlled, Phase III clinical trials, consisting of two 12-week studies, two nine-week studies, and a four week study, of approximately 1,200 patients and provided statistically significant improvements in wakefulness in those with excessive sleepiness associated with SWD, treated OSA and narcolepsy.</p> <p>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).</p>
<b>How does PROVIGIL affect sleep?</b>	In clinical trials, PROVIGIL did not adversely affect sleep as measured by polysomnography, although five percent of patients reported insomnia.
<b>What are the recommended doses of PROVIGIL?</b>	The recommended dose of PROVIGIL is 200 mg given once a day. For patients with narcolepsy and treated OSA, PROVIGIL should be taken as a single dose in the morning. For patients with SWD, PROVIGIL should be taken approximately one hour prior to the start of their work shift. Doses up to 400 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 200 mg dose.
<b>Does PROVIGIL have the potential for abuse?</b>	PROVIGIL is a federally controlled substance (C-IV) because it can be abused or lead to dependence. PROVIGIL should be kept in a safe place to prevent misuse and abuse. Selling or giving away PROVIGIL 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.
<b>What important information should patients know about PROVIGIL?</b>	<p><b>What is PROVIGIL?</b> PROVIGIL is a prescription medicine used to improve wakefulness in adults who are very sleepy due to one of the following diagnosed sleep disorders:</p> <ul style="list-style-type: none"><li>• Narcolepsy</li><li>• Obstructive sleep apnea (OSA). PROVIGIL is used with other medical treatments for this sleep disorder. PROVIGIL does not take the place of using your CPAP machine or other treatments that your doctor has prescribed for this condition. It is important that you continue to use these treatments as prescribed by your doctor.</li><li>• Shift work disorder (SWD)</li></ul> <p>PROVIGIL will not cure these sleep disorders. PROVIGIL may help the sleepiness caused by these conditions, but it may not stop all your sleepiness. PROVIGIL does not take the place of getting enough sleep. Follow your doctor's advice about good sleep habits and using other treatments.</p>

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



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

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

### What are possible side effects of PROVIGIL?

Stop taking PROVIGIL and call your doctor right away 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, other mental problems
- Symptoms of a heart problem, including: chest pain, abnormal heart beats, and trouble breathing.

Common side effects of PROVIGIL are headache, nausea, feeling nervous, stuffy nose, diarrhea, back pain, feeling anxious, trouble sleeping, dizziness, and upset stomach. These are not all the side effects of PROVIGIL. 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 PROVIGIL?

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

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

- 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 PROVIGIL. Talk to your doctor about other birth control methods while taking PROVIGIL.

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

It is important to know that PROVIGIL 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, call 1-800-896-5855, or go to [www.PROVIGIL.com](http://www.PROVIGIL.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 PROVIGIL.

How long has PROVIGIL been available?

PROVIGIL was approved in the United States in 1998 and has been on the market since 1999.



**Who makes PROVIGIL?**

Cephalon Inc. (Nasdaq: CEPH), Frazer, PA, an international biopharmaceutical company, holds exclusive rights to market and develop PROVIGIL 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 PROVIGIL is available from Cephalon Medical Services (800-896-5855) or at [www.PROVIGIL.com](http://www.PROVIGIL.com)

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