PATIENT INFORMATION

PROVIGIL® (pro-vij-el) Tablets [C-IV]
Generic name: modafinil

Read the Patient Information that comes with PROVIGIL before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment.

What is the most important information I should know about PROVIGIL?

1. PROVIGIL may cause you to have a serious rash or a serious allergic reaction. Stop PROVIGIL and call your doctor right away or get emergency treatment if you have any of the following:

- skin rash, hives, sores in your mouth, or your skin blisters and peels
- swelling of your face, eyes, lips, tongue, or throat
- trouble swallowing or breathing
- hoarse voice

2. PROVIGIL is not approved for use in children.

What is PROVIGIL?

PROVIGIL is a prescription medicine used to improve awakeness in adults who are very sleepy due to one of the following diagnosed sleep problems:

- shift work sleep disorder (SWSD)
- obstructive sleep apnea/hypopnea syndrome (OSAHS). PROVIGIL is used along with other medical treatments for this sleep problem. PROVIGIL is not a replacement for your CPAP machine. It is important that you continue to use your CPAP machine while sleeping.
- narcolepsy

You should be diagnosed with one of these sleep disorders before taking PROVIGIL. Sleepiness can be a symptom of other medical conditions that need to be treated.

- PROVIGIL will not cure the above 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.

PROVIGIL is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep PROVIGIL in a safe place to prevent misuse and abuse. Selling or giving away PROVIGIL may harm others, and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take PROVIGIL?

Do not take PROVIGIL if you:

- are allergic to any of its ingredients. The active ingredient is modafinil. See the end of this leaflet for a complete list of ingredients.
- have had a rash or allergic reaction to armodafinil, the active ingredient in NUVIGIL™, because these medicines are very similar.

PROVIGIL is not approved for use in children.

What should I tell my doctor before starting PROVIGIL?

Tell your doctor about all of your health conditions including, if you:

- have a history of mental health problems
- have heart problems or had a heart attack
- have high blood pressure
- have liver or kidney problems
- have a history of drug or alcohol abuse or addiction
- have ever had a mental problem called psychosis.
- are pregnant or planning to become pregnant. It is not known if PROVIGIL may harm your unborn baby.
- are breastfeeding. It is not known if PROVIGIL passes into your milk or if it can harm your baby.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. PROVIGIL and many other medicines can interact with each other, sometimes causing side effects. PROVIGIL may affect the way other medicines work, and other medicines may affect how PROVIGIL works. Especially, tell your doctor if you use a hormonal birth control method. PROVIGIL can affect hormonal birth control methods. Hormonal birth control methods include pills, shots, implants, patches, vaginal rings, and intrauterine devices (IUDs). Women who use hormonal birth control with PROVIGIL may have a higher chance for getting pregnant while taking PROVIGIL, and for one month after stopping PROVIGIL. Talk to your doctor about birth control methods that are right for you while using PROVIGIL.

Keep a list of all the medicines you take. Your doctor or pharmacist will tell you if it is safe to take PROVIGIL and other medicines together. Do not take other medicines with PROVIGIL unless your doctor has told you it is okay.

How should I take PROVIGIL?

- Take PROVIGIL exactly as prescribed by your doctor. Your doctor will prescribe the dose of PROVIGIL that is right for you. Do not change your dose of PROVIGIL without talking to your doctor. Do not take more PROVIGIL than prescribed.
- Your doctor will tell you the right time of day to take PROVIGIL.
  - Patients with narcolepsy or OSAHS usually take one dose of PROVIGIL every day in the morning.
  - Patients with SWSD usually take PROVIGIL about 1 hour before their work shift. Do not change the time of day you take PROVIGIL unless you have talked to your doctor. If you take PROVIGIL too close to your bedtime, you may find it harder to go to sleep.
  - You can take PROVIGIL with or without food.
- If you take more than your prescribed dose or overdose, call your doctor or poison control center right away.

What should I avoid while taking PROVIGIL?

- Do not drive a car or do other dangerous activities until you know how PROVIGIL affects you. People with sleep disorders should always be careful about doing things that could be dangerous. Do not change your daily habits until your doctor tells you it is okay.
- Avoid drinking alcohol.

What are the possible side effects of PROVIGIL?

PROVIGIL may cause serious side effects. Call your doctor or get emergency help if you get any of the following:

- **a serious rash or serious allergic reaction.** (See, "What is the most important information I should know about PROVIGIL.")
- **mental (psychiatric) symptoms.** Symptoms include depression, anxiety, hallucinations, mania, thoughts of suicide or other mental problems.
- **heart problems including chest pain**

The most common side effects of PROVIGIL are headache, nausea, nervousness, stuffy nose, diarrhea, back pain, anxiety, trouble sleeping, dizziness, and upset stomach.

PROVIGIL may cause allergic reactions. If you get a rash, hives or other allergic reaction, stop taking PROVIGIL and call your doctor right away.

If you have either of the problems listed below or any other serious side effects while taking PROVIGIL stop taking PROVIGIL and call your doctor or get emergency help:

- chest pain.
- mental problems.

Some effects of PROVIGIL on the brain are the same as other medicines called "stimulants". These effects may lead to abuse or dependence on PROVIGIL. Before

starting PROVIGIL, tell your doctor if you have ever abused drugs, including other stimulant medicines.

Tell your doctor if you get any side effect that bothers you or that does not go away while taking PROVIGIL.

These are not all the side effects of PROVIGIL. For more information, ask your doctor or pharmacist.

How should I store PROVIGIL?

- Store PROVIGIL at room temperature, 68° to 77° F (20° to 25° C).
- Keep PROVIGIL and all medicines out of the reach of children.

General information about PROVIGIL

Medicines are sometimes prescribed for conditions that are not listed in patient information leaflets. Do not use PROVIGIL for a condition for which it was not prescribed. **Do not give PROVIGIL to other people, even if they have the same symptoms you have. It may harm them and it is against the law.**

This leaflet summarizes the most important information about PROVIGIL. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about PROVIGIL that is written for health professionals. For more information, please call 1-800-896-5855, or go to www.PROVIGIL.com.

What are the ingredients in PROVIGIL?

Active Ingredient: modafinil

Inactive Ingredients: croscarmellose sodium, lactose, magnesium stearate, microcrystalline cellulose, povidone, and pregelatinized starch.

Rx Only

August 2007

Manufactured for:

Cephalon, Inc. Frazer, PA 19355

This Patient Information Leaflet has been approved by the U.S. Food and Drug Administration.