

**PATIENT INFORMATION**  
**NUVIGIL<sup>®</sup> (nu-vij-el) Tablets [C-IV]**  
**Generic name: armodafinil**

Read the Patient Information that comes with NUVIGIL 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 NUVIGIL?**

**1. NUVIGIL may cause you to have a serious rash or a serious allergic reaction. Stop NUVIGIL 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. NUVIGIL has not been studied in children under the age of 17. NUVIGIL is not approved for children for any condition.**

**What is NUVIGIL?**

NUVIGIL is a prescription medicine used to improve awakesness 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). NUVIGIL is used along with other medical treatments for this sleep problem. NUVIGIL 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 NUVIGIL. Sleepiness can be a symptom of other medical conditions that need to be treated.

- NUVIGIL will not cure the above sleep disorders. NUVIGIL may help the sleepiness caused by these conditions, but it may not stop all your sleepiness.
- NUVIGIL does not take the place of getting enough sleep.
- Follow your doctor's advice about good sleep habits and using other treatments.

NUVIGIL is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep NUVIGIL in a safe place to prevent misuse and abuse. Selling or giving away NUVIGIL 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 NUVIGIL?**

Do not take NUVIGIL if you:

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

It is not known if NUVIGIL works in or is safe for use in children under 17 years old.

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

**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 NUVIGIL may harm your unborn baby.
- are breastfeeding. It is not known if NUVIGIL 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. NUVIGIL and many other medicines can interact with each other, sometimes causing side effects. NUVIGIL may affect the way other medicines work, and other medicines may affect how NUVIGIL works. Especially, tell your doctor if you use a hormonal birth control method. NUVIGIL 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 NUVIGIL may have a higher chance for getting pregnant while taking NUVIGIL, and for one month after stopping NUVIGIL. Talk to your doctor about birth control methods that are right for you while using NUVIGIL.

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

### **How should I take NUVIGIL?**

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

- Do not drive a car or do other dangerous activities until you know how NUVIGIL 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 NUVIGIL?**

**NUVIGIL 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 NUVIGIL?”)
- **mental (psychiatric) symptoms.** Symptoms include depression, anxiety, hallucinations, mania, thoughts of suicide, aggression, or other mental problems.
- **heart problems including chest pain**

The most common side effects of NUVIGIL are headache, nausea, dizziness, and trouble sleeping.

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

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

- chest pain.
- mental problems.

Some effects of NUVIGIL on the brain are the same as other medicines called “stimulants”. These effects may lead to abuse or dependence on NUVIGIL. Before starting NUVIGIL, 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 NUVIGIL.

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

### **How should I store NUVIGIL?**

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

### **General information about NUVIGIL**

Medicines are sometimes prescribed for conditions that are not listed in patient information leaflets. Do not use NUVIGIL for a condition for which it was not prescribed. **Do not give NUVIGIL 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 NUVIGIL. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about NUVIGIL that is written for health professionals. For more information, please call 1-800-896-5855, or go to [www.NUVIGIL.com](http://www.NUVIGIL.com).

### **What are the ingredients in NUVIGIL?**

**Active Ingredient:** armodafinil

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

### **Rx Only**

January 2010

NUVPIL - 004

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