

## MEDICATION GUIDE

### Modafinil (moe daf' i nil) Tablets, USP C-IV

Read this Medication Guide before you start taking modafinil tablets and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment.

#### **What is the most important information I should know about Modafinil tablets?**

**Modafinil tablets 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.**

#### **Stop taking modafinil tablets and call your doctor right away or get emergency help if you have any of these symptoms:**

- 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
- fever, shortness of breath, swelling of the legs, yellowing of the skin or whites of the eyes, or dark urine.

If you have a severe rash with modafinil, stopping the medicine may not keep the rash from becoming life-threatening or causing you to be permanently disabled or disfigured.

#### **Modafinil tablets are not approved for use in children for any medical condition.**

It is not known if modafinil tablets are safe or effective in children under 17-years of age.

#### **What are Modafinil tablets?**

Modafinil tablets are a prescription medicine used to improve wakefulness in adults who are very sleepy due to one of the following diagnosed sleep disorders:

- narcolepsy
- obstructive sleep apnea (OSA). Modafinil tablets are used to treat excessive sleepiness, but not the obstruction or medical condition that is causing OSA. You should talk with your doctor about treatments for OSA before you start taking modafinil tablets and during treatment with modafinil. Modafinil tablets do not take the place of treatments that your doctor has prescribed for OSA. It is important that you continue to use these treatments as prescribed by your doctor.
- shift work disorder (SWD)

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

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

##### **Do not take modafinil tablets if you:**

- are allergic or developed a rash to modafinil or armodafinil (NUVIGIL®) or any of the ingredients in modafinil tablets. See the end of this Medication Guide for a complete list of ingredients in modafinil tablets.

#### **What should I tell my doctor before taking Modafinil tablets?**

##### **Tell your doctor about all of your medical conditions including, if you:**

- have a history of mental health problems, including psychosis
- have heart problems or had a heart attack
- have high blood pressure. Your blood pressure may need to be checked more often while taking modafinil tablets.
- have liver or kidney problems
- have a history of drug or alcohol abuse or addiction
- are pregnant or planning to become pregnant. It is not known if modafinil will harm your unborn baby.

#### **Pregnancy Registry:**

There is a registry for women who become pregnant during treatment with modafinil tablets. The purpose of this registry is to collect information about the safety of modafinil tablets during pregnancy. Contact the registry as soon as you learn that you are pregnant, or ask your doctor to contact the registry for you. You or your doctor can get information and enroll you in the registry by calling 1-866-404-4106.

- are breastfeeding. It is not known if modafinil passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take modafinil tablets.

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Modafinil and many other medicines can interact with each other, sometimes causing side effects. Modafinil may affect the way other medicines work, and other medicines may affect how modafinil works. Your dose of modafinil or certain other medicines may need to be changed.

Especially, tell your doctor if you use or take:

- a hormonal birth control method, such as birth control pills, shots, implants, patches, vaginal rings, and intrauterine devices (IUDs). Hormonal birth control methods may not work while you take modafinil. Women who use one of these methods of birth control may have a higher chance for getting pregnant while taking modafinil, and for one month after stopping modafinil. Talk to your doctor about birth control choices that are right for you while taking modafinil.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine. Your doctor or pharmacist will tell you if it is safe to take modafinil and other medicines together. Do not start any new medicines with modafinil unless your doctor has told you it is okay.

### How should I take Modafinil tablets?

- Take modafinil tablets exactly as prescribed by your doctor. Your doctor will prescribe the dose of modafinil tablets that is right for you. Do not change your dose of modafinil tablets without talking to your doctor.
- Your doctor will tell you the right time of day to take modafinil tablets.
  - o People with narcolepsy or OSA usually take modafinil tablets 1-time each day in the morning.
  - o People with SWD usually take modafinil tablets about 1-hour before their work shift.
- Do not change the time of day you take modafinil tablets unless you have talked to your doctor. If you take modafinil tablets too close to your bedtime, you may find it harder to go to sleep.
- You can take modafinil tablets with or without food.
- If you take more than your prescribed dose or if you take an overdose of modafinil tablets, call your doctor or go to the nearest hospital emergency room right away.

Symptoms of an overdose of modafinil tablets may include:

- trouble sleeping
- restlessness
- confusion
- feeling disoriented
- feeling excited
- hearing, seeing, feeling, or sensing things that are not really there (hallucinations)
- nausea and diarrhea
- a fast or slow heartbeat
- chest pain
- increased blood pressure

### What should I avoid while taking Modafinil tablets?

- Do not drive a car or do other dangerous activities until you know how modafinil 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.
- You should avoid drinking alcohol. It is not known how drinking alcohol will affect you when taking modafinil tablets.

### What are possible side effects of Modafinil tablets?

**Modafinil tablets may cause serious side effects.** Stop taking modafinil tablets and call your doctor right away 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 Modafinil tablets?”)
- **mental (psychiatric) symptoms, including:**
  - o depression
  - o feeling anxious
  - o hearing, seeing, feeling, or sensing things that are not really there (hallucinations)
  - o an extreme increase in activity and talking (mania)
  - o thoughts of suicide
  - o aggressive behavior
  - o other mental problems
- **symptoms of a heart problem,** including chest pain, abnormal heartbeat, and trouble breathing.

Common side effects that can happen in anyone who takes modafinil tablets include:

- headache
- back pain
- nausea
- feeling nervous
- stuffy nose
- diarrhea
- feeling anxious
- trouble sleeping
- dizziness
- upset stomach

**Modafinil tablets are not approved for use in children** for any medical condition including Attention Deficit Hyperactivity Disorder (ADHD). In studies of modafinil tablets in children with narcolepsy, side effects included:

- Tourette’s syndrome
- hostile behavior
- increase in sudden loss of muscle tone and severe muscle weakness
- increase in seeing and hearing things when falling asleep
- increase in suicidal thoughts
- low white blood count
- painful menstrual periods

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

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

Some effects of modafinil tablets on the brain are the same as other medicines called “stimulants”. These effects may lead to abuse or dependence on modafinil tablets.

Call your doctor for medical advice about side effects. You may report side effects to Viona Pharmaceuticals Inc. at 1-888-304-5011 or FDA at 1-800-FDA-1088.

**How should I store Modafinil tablets?**

- Store modafinil at room temperature between 68°F and 77° F (20°C and 25° C).
- Modafinil tablets come in child-resistant bottle pack of 30's and 90's.
- **Keep modafinil tablets and all medicines out of the reach of children.**

**General information about the safe and effective use of Modafinil tablets.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use modafinil tablets for a condition for which it was not prescribed. Do not give modafinil tablets to other people, even if they have the same symptoms you have. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about modafinil tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about modafinil tablets that is written for health professionals.

**What are the ingredients in Modafinil tablets?**

**Active Ingredient:** modafinil, USP

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

Medication Guide available at [www.vionausa.com/medguides](http://www.vionausa.com/medguides) or call 1-888-304-5011.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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