



**Primus Ray
Laboratories**

Modafinil 50mg

Modafinil 50 is approved for use for the following indications:

Modafinil is a medication that promotes wakefulness.

Modafinil is used to treat excessive sleepiness caused by sleep apnea, narcolepsy, or shift work sleep disorder.

Modafinil may also be used for purposes not listed in this medication guide.

Chemical: Modafinil 50mg/tb
CAS Name: 2-[(Diphenylmethyl)sulfinyl]-acetamide
Molecular Formula: C₁₅H₁₅NO₂S
Molecular Weight: 273.35
Prescription Medicine

Modafinil 50
Each uncoated tablet contains:
Modafinil USP 50mg

INDICATION AND USES

You should not use this medication if you are allergic to modafinil or armodafinil (Nuvigil).

Before using modafinil, tell your doctor if you have angina (chest pain), liver or kidney disease, a heart problem, a history of drug addiction, if you take blood pressure medication, or if you have recently had a heart attack.

Modafinil affects the central nervous system. This medication may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be alert. Avoid other dangerous activities until you know how this medication will affect your level of wakefulness.

Stop taking modafinil and call your doctor if you have a skin rash, no matter how mild. A medicine similar to modafinil has caused severe skin reactions serious enough to require hospitalization. Other signs of a severe reaction include fever, sore throat, headache, and vomiting with a severe blistering, peeling, and red skin rash.

There may be other drugs that can interact with modafinil. Tell your doctor about all medications you use. This includes prescription, over-the-counter, vitamin, and herbal products. Do not start a new medication without telling your doctor.

CONTRAINDICATIONS

You should not use this medication if you are allergic to modafinil or armodafinil (Nuvigil).

To make sure you can safely take modafinil, tell your doctor if you have any of these other conditions:

- angina (chest pain);
- cirrhosis or other liver problem;
- kidney disease;
- a heart muscle or valve disorder such as mitral valve prolapse;
- a history of drug addiction;
- if you take blood pressure medications; or
- if you have recently had a heart attack.

Skin rashes serious enough to require hospitalization have occurred in people using a medicine similar to modafinil. These rashes usually occurred within 1 to 5 weeks after the first dose.

FDA pregnancy category C. It is not known whether modafinil will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant while using this medication.

Stop taking modafinil and call your doctor at the first sign of any skin rash, no matter how minor you think it might be.

It is not known whether modafinil passes into breast milk or if it could harm a nursing baby. Do not use this medication without telling your doctor if you are breast-feeding a baby.

Modafinil can make certain types of birth control pills less effective, which could result in an unplanned pregnancy. Talk with your doctor about the best methods of birth control to use while taking modafinil.

Do not give modafinil to anyone younger than 16 years old.

SIDE EFFECTS

Get emergency medical help if you have any of these signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Stop using modafinil and call your doctor at once if you have any of these serious side effects:

- fever, sore throat, headache, and vomiting with a severe blistering, peeling, and red skin rash;
- bruising, severe tingling, numbness, pain, muscle weakness;
- easy bruising or bleeding;
- white patches or sores inside your mouth or on your lips;
- hallucinations, unusual thoughts or behavior;
- depression, anxiety, aggression; or
- chest pain, uneven heart beats.

Less serious side effects may include:

- headache, dizziness;
- feeling nervous or agitated;
- nausea, diarrhea;
- trouble sleeping (insomnia); or
- dry mouth.

DOSAGE AND ADMINISTRATION

Take exactly as prescribed by your doctor. Do not take in larger or smaller amounts or for longer than recommended. Modafinil is usually given for 12 weeks or less. Follow the directions on your prescription label.

This medication comes with patient instructions for safe and effective use. Follow these directions carefully. Ask your doctor or pharmacist if you have any questions.

Modafinil is usually taken each morning to prevent daytime sleepiness, or 1 hour before the start of a work shift to treat work-time sleep disorders.

If you are taking modafinil to treat sleepiness caused by obstructive sleep apnea, you may also be treated with a continuous positive airway pressure (CPAP) machine. This machine is an air pump connected to a mask that gently blows pressurized air into your nose while you sleep. The pump does not breathe for you, but the gentle force of air helps keep your airway open to prevent obstruction.

Do not stop using your CPAP machine during sleep unless your doctor tells you to. The combination of treatment with CPAP and modafinil may be necessary to best treat your condition.

Modafinil will not cure obstructive sleep apnea or treat its underlying causes. Follow your doctor's instructions about all your other treatments for this disorder.

Talk with your doctor if you continue to have excessive sleepiness even while taking modafinil.

Taking this medication does not take the place of getting enough sleep.

Store at room temperature away from moisture and heat.
What happens if I miss a dose?

Take the missed dose as soon as you remember, but avoid taking the medication if you do not plan to be awake for several hours. If it is close to your normal bedtime hour, you may need to skip the missed dose and wait until the next day to take the medicine again.

Talk with your doctor about what to do if you miss a dose of modafinil. Do not take extra medicine to make up the missed dose.

PRESENTATION:

50mg tablets in blister packs of 25 tablets – 2 packs per box (50 tablets)

STORAGE

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.