

(100 % EXPORT QUALITY MEDICINE

# **GENERIC NAME:** modafinil

## DRUG CLASS AND MECHANISM

Modafinil is an oral drug that is used for improving wakefulness in patients with excessive sleepiness. The effect of modafinil is similar to caffeine. Both drugs promote wakefulness by stimulating the brain. Thus, both drugs are considered stimulants. Other stimulants, for example, dextroamphetamine (Dexedrine) and sibutramine (Meridia), also have the different effect of suppressing appetite. All four of these drugs affect the neurotransmitters in the brain, the chemicals that the nerves of the brain use to communicate with each other; however, they affect the neurotransmitters differently. Modafinil was approved by the FDA in December, 1998.

### PRESCRIPTION: Yes

PREPARATIONS: Tablets: 100 mg and 200 mg.

#### PRESCRIBED FOR

**Modafinil** is used to promote wakefulness in patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome (as an adjunct for treatment of the underlying obstruction), and shiftwork sleep disorder. Narcolepsy is a chronic disease of the brain and spinal cord characterized most commonly by a recurrent, uncontrollable desire to sleep. Shiftwork sleep disorder is a condition in which the normal rhythm of sleep is disturbed, often as a result of working at night.

#### DOSING

**Modafinil** usually is taken at a dose of 200 or 400 mg daily, although the 400 mg dose has not been shown to be more effective than the 200 mg dose. Modafinil can be taken with or without food.

# DRUG INTERACTIONS

**Modafinil** can decrease or increase the activity of enzymes in the liver that metabolize (eliminate) other drugs. This can result in decreased levels of some drugs that reduce their effectiveness and increased levels of other drugs that leads to their toxicity. Modafinil treatment should be carefully monitored if taken with any of these drugs.

Drugs which may have reduced effectiveness if taken with modafinil include cyclosporine (Sandimmune), theophylline, and hormonal contraceptives such as progestin-only or estrogen and progesterone containing drugs (e.g., Micronor, Ortho-Novum 1/50). Alternative hormonal contraceptives or an additional non-drug form of contraception should be considered during treatment with modafinil, and treatment should continue for one month after modafinil therapy ends (since the effects of modafinil on contraceptive hormonal contraceptives occurs if the hormones are taken by mouth, patch, or implant.

Drugs that may show increased effects or toxicity if taken with modafinil include warfarin (Coumadin), diazepam (Valium), propranolol (Inderal), imipramine (Tofranil), desipramine (Norpramin), phenytoin (Dilantin) and mephenytoin (Mesantoin).

Some other drugs that may increase the effectiveness and/or toxicity of modafinil. These drugs include carbamazepine (Tegretol), phenobarbital, and rifampin (Rifadin). Other drugs, such as ketoconazole (Nizoral) and itraconazole (Sporanox) may reduce the effectiveness of modafinil.

It is not clear if there are interactions between modafinil and alcohol.

#### USES

This medication is used to treat excessive daytime sleepiness associated with narcolepsy, problems breathing while asleep (sleep apnea/hypopnea syndrome-OSAHS), or shift work sleep disorder (SWSD).

#### HOW TO USE

Take by mouth, in the morning, as directed. Use this medication exactly as prescribed. Do not increase your dose, take it more frequently or use it for a longer period of time than prescribed because this drug can be habit-forming. Also, do not stop using this drug without your doctor's approval.

# SIDE EFFECTS

Nausea, diarrhea or headache may occur. If these effects persist or worsen, notify your doctor promptly. Report promptly: trouble sleeping, dizziness, mental/mood changes, loss of appetite, dry mouth. Unlikely but report promptly chest pain, fast/irregular pulse, vision changes, increased thirst/urination, trouble with urination, trouble with ejaculation, unusual muscle weakness or stiffness, muscle tingling or twitching. In the unlikely event you have an allergic reaction to this medication, seek immediate medical attention. Symptoms of an allergic reaction include: rash, itching, swelling, dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

# PRECAUTIONS

Tell your doctor your medical history, including: mental/mood problems, high blood pressure, heart problems, liver problems, kidney problems, allergies (especially drug allergies). Avoid alcohol intake, as it may intensify certain side effects of this drug. Caution is advised when performing tasks requiring alertness (e.g., driving). Caution is advised when this drug is used in the elderly, as they may be more prone to drug side effects. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug is excreted into breast milk. Consult your doctor before breast-feeding.

# OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose include fast heartbeat, trouble sleeping, agitation, and restlessness.

### **MISSED DOSE**

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

#### STORAGE

Store at room temperature between 68 and 77 degrees F (20 to 25 degrees C) away from light and moisture.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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Revised November 2010