

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrMODAFINIL

Modafinil Tablets, USP

Read this carefully before you start taking **MODAFINIL** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MODAFINIL**.

What is MODAFINIL used for?

MODAFINIL is used to treat adults who are very sleepy due to one of the following medical conditions:

- **Narcolepsy:** A sleep disorder characterized by sudden attacks of sleep that cannot be controlled.
- **Obstructive Sleep Apnea (OSA):** A disorder where the muscles in the throat temporarily relax causing breathing problems during sleep. MODAFINIL is used along with other medical treatments for this sleep problem. MODAFINIL is not a replacement for other treatments that have been prescribed for OSA. It is important that you continue to use these treatments as prescribed by your healthcare professional.
- **Shift Work Disorder (SWD):** A circadian rhythm sleep disorder characterized by very strong feelings of sleepiness when working long hours or irregular schedules outside the normal sleep period.

MODAFINIL is not approved for use in children for any medical condition.

How does MODAFINIL work?

MODAFINIL belongs to a group of medicines called central nervous system (CNS) stimulants. The exact way that MODAFINIL works is not known. However, it is thought to stimulate your brain to promote mental and physical processes.

What are the ingredients in MODAFINIL?

Medicinal ingredient: Modafinil.

Non-medicinal ingredients: Crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, mannitol and povidone.

MODAFINIL comes in the following dosage forms:

Tablets; 100 mg of modafinil.

Do not use MODAFINIL if:

- you are allergic to modafinil, armodafinil, or to any other ingredient in MODAFINIL.
- you have severe anxiety (feel very worried, nervous, or stressed) or are very agitated.

- you are pregnant or plan to become pregnant.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MODAFINIL. Talk about any health conditions or problems you may have, including if you:

- are using a hormonal birth control method (e.g., birth control pills, shots, implants, intrauterine devices (IUDs), or patches).
- have high blood pressure.
- have or have had heart or blood vessel problems (e.g., coronary artery disease, heart attacks, unstable angina, and irregular heart beat or rhythm).
- have liver problems.
- have kidney problems.
- have or had a mental health problem.
- have ever had a problem with substance use, including prescribed or illegal drugs, or stimulants (e.g., methylphenidate, amphetamine, or cocaine).
- have one of the following rare genetic conditions:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorptionLactose is a non-medicinal ingredient in MODAFINIL.
- have had an allergic reaction to other medicines.
- are breastfeeding or plan to breastfeed. MODAFINIL can be passed into breast milk.
- are over the age of 65 years old.
- are drinking or plan to drink alcohol. Avoid consuming alcohol while taking MODAFINIL. It is not known how drinking alcohol will affect you when taking MODAFINIL.

Other warnings you should know about:

Taking MODAFINIL can cause the following:

- **Arrhythmia** (abnormal heart beats): This can include arrhythmia caused by atrial fibrillation and premature ventricular contractions.
- **Hypertension** (high blood pressure)
- **Myocardial ischemia** (lack of blood flow to the heart which can lead to heart attack): It is more likely to develop myocardial ischemia if you:
 - have coronary artery disease,
 - have had a recent heart attack, or
 - have unstable angina (not enough oxygen to the heart muscle).
- **Stroke** (bleeding or blood clot in the brain)
- **Mental and behavioural changes:** This can include worsening of emotional or behaviour problems, psychotic episodes, mania, delusions, hallucinations, suicidal ideation and aggression. It is more likely to develop mental and behavioural changes if you have had a previous mental health problem.
- **Severe allergic reactions:** This can include swelling of face, eyes, lips, tongue or larynx; difficulty in swallowing or breathing; or a hoarse voice. In severe cases the

allergic reaction may affect multiple organs, which can be potentially life-threatening. If any type of allergic reaction is suspected, stop taking MODAFINIL right away.

- **Severe skin reactions:** This can include Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), and Drug Rash with Eosinophilia and Systemic Symptoms (DRESS). These are rare, but serious and potentially fatal skin reactions that may require hospitalization.

See the **Serious side effects and what to do about them** table, below, for more information on these and other serious side effects.

Abuse and misuse: Taking MODAFINIL can put you at risk for abuse and misuse, especially if you have a history of substance abuse. Your healthcare professional will monitor your risk for these behaviours. However, if you notice any signs of abuse or misuse (e.g., if you have a craving for MODAFINIL), tell your healthcare professional right away.

Sleepiness: MODAFINIL may help to treat your sleepiness, but it may not stop all of your sleepiness. Discuss your level of sleepiness with your healthcare professional during each visit.

Pregnancy:

- Do not take MODAFINIL if you are pregnant as it can harm your unborn baby. If you get pregnant or think you are pregnant while taking MODAFINIL or within two months after stopping MODAFINIL, tell your healthcare professional right away.
- If you are able to get pregnant you must take a pregnancy test before starting MODAFINIL. A negative pregnancy result should be obtained at least a week prior to starting your treatment with MODAFINIL. It is recommended that you take pregnancy tests throughout your treatment to allow the early detection of pregnancy.
- MODAFINIL can reduce the effects of certain hormonal birth control methods used to prevent pregnancy. These methods can include birth control pills, shots, implants, intrauterine devices (IUDs), or patches. Talk to your healthcare professional to find about the appropriate methods of contraception.

Driving and using machines: MODAFINIL can cause over-stimulation and overconfidence. Before you drive or do tasks that require special attention, wait until you are certain that MODAFINIL does not affect your ability to engage in these activities.

Monitoring and testing: Your healthcare professional will perform various tests, such as an electrocardiogram (ECG), to monitor your health before, during and after your treatment. This will tell your healthcare professional about your heart, blood profile, blood pressure, and heart rate. They will use this information to determine if MODAFINIL is right for you and how it is affecting you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MODAFINIL:

- antidepressants used to treat depression (such as clomipramine, selective serotonin reuptake inhibitors (SSRI), tricyclic antidepressants, and monoamine oxidase (MAO) inhibitors).

- antipyrine, used to treat ear infection pain.
- cyclosporine, used to suppress the immune system.
- other central nervous system (CNS) stimulants used to stimulate the brain (such as dextroamphetamine, methylphenidate, and amphetamines).
- oral birth control (“the pill”).
- anticonvulsants used to prevent or treat seizures (such as phenytoin, S-mephenytoin, and diazepam).
- medicines that belong to a group of medicines called sympathomimetics.
- propranolol, used to treat heart problems.
- warfarin, used to thin the blood and prevent blood clots.
- triazolam, used to treat insomnia (sleep disorder that makes it hard to fall asleep).

How to take MODAFINIL:

- Take MODAFINIL by mouth exactly as prescribed by your healthcare professional. Do not change your dose or the time of day you take MODAFINIL without talking to your healthcare professional.
- MODAFINIL does not take the place of getting enough sleep. Follow your healthcare professional’s advice about good sleeping habits.
- You may not feel like MODAFINIL is working right away. It may take an hour or so before you feel the effects.

Usual dose:

Your healthcare professional will determine the right dose and time of day for you depending on your condition. Check with them if you are not sure.

The usual adult daily doses are as follows:

- **Narcolepsy:** One to two tablets (100 mg to 200 mg) in the morning and one to two tablets (100 mg to 200 mg) at noon.
- **Obstructive Sleep Apnea (OSA):** Two tablets (200 mg) in the morning, in addition to the other prescribed medical treatment(s) for OSA.
- **Shift Work Disorder (SWD):** Two tablets (200 mg) about 1 hour before the start of the work shift.

It is not recommended to take more than three tablets (300 mg) at one time or four tablets (400 mg) a day.

Overdose:

An overdose with MODAFINIL can cause:

- trouble sleeping;
- feeling restless or agitated;
- feeling disoriented;
- feeling confused;
- feeling anxious;
- feeling excited;

- hearing, seeing, feeling or sensing things that are not really there (hallucination);
- nausea;
- diarrhea;
- fast or slow heartbeat;
- increase in blood pressure;
- chest pain.

If you think you, or a person you are caring for, have taken too much MODAFINIL, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget or miss a dose of MODAFINIL, take the dose as soon as you remember unless it is close to the time of your next dose. If it is close to the time of your next dose, skip the missed dose and take the next dose at the usual scheduled time. Taking MODAFINIL in the evening or the late afternoon may prevent from falling asleep at usual bedtime, and should, therefore, be avoided. If you are unsure what to do, talk to your healthcare professional.

What are possible side effects from using MODAFINIL?

These are not all the possible side effects you may have when taking MODAFINIL. If you experience any side effects not listed here, contact your healthcare professional.

Common side effects may include:

- back pain,
- diarrhea,
- difficulty falling asleep,
- drowsiness,
- nervousness,
- sleepiness,
- stuffy nose, or
- upset stomach.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Arrhythmia (abnormal heart rhythms): rapid, slow or irregular heartbeat.			√
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations.			√
UNCOMMON			
Heart arrest: chest discomfort, shortness of breath, weakness, fast-beating, fluttering or pounding heart.			√
RARE			
Myocardial ischemia (lack of blood flow to the heart which can lead to heart attack): sudden chest pain, pressure or discomfort, feeling faint, feeling anxious, shortness of breath, irregular heartbeat, nausea, or sudden heavy sweating.			√
Mental and behavioural changes: depression, anxiety, hallucinations, suicidal thoughts or actions, aggression, extreme increase in activity and talking (mania), feeling agitated, personality changes, or delusions.			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Severe skin reactions (including Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), and Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)): severe skin rash, redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, fever, chills, headache, body aches, swollen glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, feel thirsty, urinate less often, or less urine.			√
Severe allergic reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, hoarse voice, sudden wheeziness, chest pain, or chest tightness.			√
UNKNOWN FREQUENCY			
Stroke (bleeding or blood clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side of the body, sudden headache, blurry vision, difficulty swallowing or speaking, lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking, or loss of balance.			√
Agranulocytosis (decrease in white blood cells): frequent infection with fever, chills, or sore throat.		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage

- Store MODAFINIL tablets at room temperature (15°C to 30°C). Protect from moisture.
- Do not use expired medication.
- Keep MODAFINIL in a safe place to prevent misuse or abuse.
- Keep out of reach and sight of children.

If you want more information about MODAFINIL:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), or by contacting Sanis Health Inc. at 1-866-236-4076 or quality@sanis.com.

This leaflet was prepared by

Sanis Health Inc.
1 President's Choice Circle
Brampton, Ontario
L6Y 5S5

Last revised: January 25, 2024.