

iMedix: Your Personal Health Advisor.

Provigil

Provigil (Modafinil) is a wakefulness-promoting medication used to treat excessive sleepiness caused by narcolepsy, obstructive sleep apnea, and shift work disorder.

- **ActiveIngredient:** Modafinil
 - **DosageForm:** Tablets
 - **Dosage:** 100 mg, 200 mg
 - **Indications:** Narcolepsy, Obstructive Sleep Apnea, Shift Work Sleep Disorder
 - **Manufacturer:** Cephalon (brand), various generics
 - **Storage:** Store at room temperature (20–25°C), protect from light and moisture
 - **Market Price:** 0.84
 - **Drug Status:** Prescription Only
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Description

Provigil (Modafinil) is a central nervous system stimulant that promotes wakefulness by altering neurotransmitters in the brain, particularly dopamine. Unlike traditional stimulants (e.g., amphetamines), modafinil has a lower risk of dependency and a different mechanism of action, making it suitable for long-term use in managing chronic sleep disorders. Approved for narcolepsy, obstructive sleep apnea, and shift work sleep disorder, Provigil helps patients stay awake during required hours without the extreme highs and crashes associated with other stimulants. It is also used off-label for conditions like ADHD and chronic fatigue syndrome, though these uses lack FDA approval. Key Features: Duration: Effects last 10–12 hours, making it ideal for shift workers or those needing prolonged alertness. Non-addictive: Classified as a Schedule IV controlled substance (lower abuse potential than Schedule II drugs). Neurochemical Action: Inhibits dopamine reuptake and may affect orexin/hypocretin pathways. Important Note Provigil does not cure sleep disorders but manages symptoms. It requires a comprehensive sleep evaluation before prescription and should be combined with lifestyle changes (e.g., sleep hygiene) for optimal results.

General Instructions

How to Take: Take Provigil once daily, typically in the morning for narcolepsy or obstructive sleep apnea. For shift work disorder, take 1 hour before starting your work shift. Swallow the tablet whole with water, with or without food. Avoid high-fat meals, as they may delay the medication's effects. **Dosage Adjustments:** Standard dose: 200 mg daily. Hepatic impairment: Reduce to 100 mg daily for severe liver disease. Elderly patients: Lower doses may be needed due to slower metabolism. Maximum dose: Do not exceed 400 mg daily, though most patients respond to 200 mg. **Missed Dose:** If you forget a dose, take it as soon as remembered. If it is close to bedtime, skip the dose to avoid insomnia. Never take extra tablets to compensate. **Storage:** Store tablets in the original container at room temperature (20–25°C). Protect from light, moisture, and heat. Keep out of reach of children and individuals without a prescription. **Important Notes:** Not a sleep replacement: Provigil promotes wakefulness but does not replace adequate sleep. Maintain good sleep hygiene. Avoid alcohol: May increase drowsiness or reduce medication effectiveness. **Drug interactions:** Inform your doctor if taking CYP3A4 inducers (e.g., carbamazepine) or inhibitors (e.g., ketoconazole), as they may require dose adjustments. **Pregnancy/breastfeeding:** Not recommended; discuss

risks with your doctor. Discontinuation: Do not stop abruptly without medical guidance, especially after long-term use. Safety Precautions: Provigil is a Schedule IV controlled substance—never share it with others. Report side effects like rapid heartbeat, mood changes, or skin rashes immediately. Avoid driving or operating machinery until you know how Provigil affects you.

Side Effects

Common Side Effects The most frequently reported side effects include headache, nausea, dizziness, and difficulty sleeping (insomnia). Some users experience nervousness, dry mouth, or gastrointestinal discomfort such as diarrhea or indigestion. These reactions are typically mild and often resolve within a few days as the body adjusts to the medication. **Less Common but Notable Effects** A small percentage of users report anxiety, blurred vision, or mild increases in heart rate. Uncommon side effects may include mood swings, sweating, or a metallic taste in the mouth. While rare, some individuals develop allergic reactions like skin rashes or itching. **Serious Side Effects** Seek immediate medical attention if you experience symptoms of a severe skin reaction (e.g., Stevens-Johnson syndrome), such as blistering, peeling skin, or mouth sores. Other critical concerns include chest pain, irregular heartbeat, hallucinations, suicidal thoughts, or signs of liver problems (dark urine, yellowing skin/eyes). Provigil may also exacerbate pre-existing mental health conditions like depression or psychosis. **Managing Side Effects** For headaches or mild nausea, over-the-counter pain relievers (e.g., acetaminophen) or taking the medication with food may help. If insomnia occurs, avoid taking Provigil late in the day and establish a consistent bedtime routine. Persistent anxiety or mood changes should be discussed with your doctor, as dose adjustments or alternative treatments may be necessary. **Special Considerations** **Pregnancy/Breastfeeding:** Potential risks to fetal development or nursing infants; use only if clearly needed. **Cardiovascular Health:** Monitor blood pressure and heart rate regularly, especially in those with pre-existing heart conditions. **Psychiatric History:** Patients with depression, bipolar disorder, or schizophrenia may require closer monitoring. **Important Note:** Provigil is not habit-forming for most users, but misuse can lead to dependence. Report any unusual or worsening symptoms to your healthcare provider promptly.

Uses

FDA-Approved Uses: Provigil is prescribed to treat excessive daytime sleepiness associated with: **Narcolepsy:** A chronic sleep disorder characterized by overwhelming daytime drowsiness and sudden sleep attacks. **Obstructive Sleep Apnea (OSA):** Used alongside continuous positive airway pressure (CPAP) therapy to manage residual sleepiness in patients already compliant with airway treatment. **Shift Work Sleep Disorder (SWSD):** Helps improve wakefulness in individuals with non-traditional work schedules (e.g., night shifts) who struggle to stay alert during work hours. **Mechanism in Sleep Disorders:** Modafinil promotes wakefulness by targeting dopamine transporters and increasing dopamine availability in the brain. It may also influence other neurotransmitters like orexin, which regulate the sleep-wake cycle. Unlike traditional stimulants, it does not cause significant euphoria or rebound fatigue. **Off-Label Uses:** While not FDA-approved, Provigil is sometimes prescribed for: **Attention Deficit Hyperactivity Disorder (ADHD):** May improve focus in adults unresponsive to standard therapies. **Chronic Fatigue Syndrome (CFS):** Used cautiously to combat persistent exhaustion. **Jet Lag:** Occasionally recommended for short-term adjustment to rapid time zone changes. **Important Considerations:** **Diagnosis Required:** Provigil should only be used after a confirmed diagnosis of a sleep disorder through clinical evaluation (e.g., polysomnography for OSA). **Adjunct Therapy:** For sleep apnea, it is not a substitute for CPAP or other airway management treatments. **Not for Sleep Deprivation:** Does not replace the need for adequate restorative sleep. **Limitations:** Not approved for pediatric use (safety under age 17 not established). Avoid in patients with uncontrolled hypertension, cardiac arrhythmias, or a history of substance abuse. Effectiveness diminishes if underlying sleep issues (e.g., untreated OSA) are not addressed. **Key Note:** Provigil is classified as a Schedule IV controlled substance due to its potential for misuse, though addiction risk is lower than with stimulants like amphetamines. It should always be used under medical supervision.

Safety advice

Interactions Alcohol:

- Use with caution
- Alcohol may counteract Provigil's wakefulness effects and worsen side effects like dizziness or drowsiness. Limit consumption to avoid impaired alertness.

Interactions Other Medications:

- Consult your doctor
- Provigil interacts with CYP3A4 inhibitors (e.g., ketoconazole) and inducers (e.g., carbamazepine), affecting its effectiveness. It may also reduce the efficacy of hormonal contraceptives. Inform your doctor about all medications, including antidepressants, blood thinners, or stimulants.

Special Groups Pregnancy:

- Consult your doctor
- Limited data exist on fetal safety. Use only if benefits outweigh risks, and avoid during pregnancy unless absolutely necessary.

Special Groups Breastfeeding:

- Unsafe
- Modafinil may pass into breast milk, posing potential risks to infants. Discuss alternative treatments with your doctor.

Special Groups Elderly:

- Use with caution
- Older adults may metabolize Provigil more slowly, increasing side effect risks (e.g., insomnia, hypertension). Lower doses or closer monitoring may be needed.

Special Groups Children:

- Unsafe
- Not approved for individuals under 17. Safety and efficacy in pediatric patients are unestablished.

Effects on Activities Driving:

- Use with caution
- Provigil may cause dizziness, blurred vision, or overconfidence in alertness. Assess your reaction to the medication before driving.

Effects on Activities Operating Machinery:

- Use with caution
- Similar to driving, ensure full alertness and coordination before handling hazardous machinery.

Concerns

Dependency and Misuse While Provigil has a lower risk of addiction compared to traditional stimulants, it is still classified as a Schedule IV controlled substance. Prolonged misuse, such as taking higher doses or using it without medical supervision, can lead to psychological dependence. Patients with a history of substance abuse should be closely monitored. **Psychiatric Effects** Provigil may exacerbate pre-existing psychiatric conditions, including anxiety, depression, or bipolar disorder. Rare cases of hallucinations, paranoia, or suicidal ideation have been reported. Patients with mental health histories require careful monitoring, and treatment should be reassessed if mood or behavior changes occur. **Cardiovascular Risks** Modafinil can increase heart rate and blood pressure, posing risks for individuals with hypertension, arrhythmias, or coronary artery disease. Regular cardiovascular monitoring is advised, especially for those with underlying

heart conditions. Severe Skin Reactions Though rare, Provigil has been linked to life-threatening skin conditions like Stevens-Johnson syndrome (SJS) or drug rash with eosinophilia and systemic symptoms (DRESS). Discontinue use immediately if a rash, blistering, or mucosal ulcers develop, and seek emergency care. Contraceptive Efficacy Provigil reduces the effectiveness of hormonal contraceptives (e.g., birth control pills, patches). Women of childbearing age should use non-hormonal contraception (e.g., barrier methods) during treatment and for 1 month after stopping to prevent unintended pregnancy. Sleep Pattern Disruption Improper timing of doses (e.g., taking it too late in the day) can lead to insomnia or fragmented sleep. Patients with shift work disorder should take it 1 hour before their shift to minimize interference with restorative sleep. Off-Label Use Uncertainties While sometimes prescribed for ADHD or chronic fatigue, these uses lack FDA approval. Risks and benefits for unapproved conditions are not well-established, and such use should only occur under strict medical supervision. Critical Reminders Provigil does not replace healthy sleep habits—prioritize adequate rest. Avoid sharing medication due to misuse potential. Long-term safety data are limited; regular follow-ups are essential.

Warnings

Absolute Contraindications Do not use Provigil if you: Have a known allergy to modafinil, armodafinil, or any tablet ingredients. Are taking monoamine oxidase inhibitors (MAOIs) for depression or Parkinson's disease (risk of severe interactions). **Black Box Warning (FDA) Severe Skin Reactions:** Provigil carries a rare but life-threatening risk of Stevens-Johnson syndrome (SJS) and drug rash with eosinophilia and systemic symptoms (DRESS). Discontinue immediately if a rash, mouth sores, or blistering occurs, and seek emergency care. **Dangerous Drug Interactions MAOIs:** Combining with MAO inhibitors (e.g., phenelzine, selegiline) may trigger hypertensive crisis. **Cytochrome P450 Interactions:** Provigil may reduce the efficacy of drugs metabolized by CYP3A4/5 (e.g., cyclosporine, some antivirals) or increase levels of CYP2C19 substrates (e.g., diazepam). **Hormonal Contraceptives:** Reduced effectiveness of birth control pills, patches, or implants (see Section B.6). **Cardiovascular Precautions** Provigil may increase heart rate and blood pressure. Avoid use if you have: Uncontrolled hypertension History of heart attack or unstable angina Severe arrhythmias **Psychiatric Risks** May worsen pre-existing mental health conditions (e.g., psychosis, mania). Monitor closely for new or worsening symptoms like aggression, hallucinations, or suicidal thoughts. **Critical Reminders** Inform your doctor about all medical conditions, including liver/kidney disease, heart issues, or psychiatric history. Disclose all medications, supplements, and herbal products you use. **Counterfeit Alert:** Fake Provigil often lacks proper warnings and may contain hazardous substances.

Dosage

Standard Adult Dosage Narcolepsy or Obstructive Sleep Apnea: Initial dose: 200 mg taken once daily in the morning. Some doctors may start with 100 mg to assess tolerance, increasing to 200 mg as needed. **Shift Work Sleep Disorder:** 200 mg taken orally 1 hour before the start of the work shift. **Dosage Adjustments Elderly or Hepatic Impairment:** Reduced doses (e.g., 100 mg daily) may be recommended due to slower metabolism. Regular monitoring of liver function may be required. **Renal Impairment:** No specific adjustment guidelines, but caution is advised. **Important Considerations Timing:** Take early in the day to avoid insomnia. **Consistency:** Do not split, crush, or alter tablets. Swallow whole with water. **Duration:** Use only as long as prescribed. Long-term use requires periodic evaluation. **Overdose Symptoms** may include severe agitation, confusion, rapid heartbeat, or hallucinations. Seek emergency care immediately. Do not attempt to induce vomiting unless instructed by a medical professional. **Critical Notes** Never self-adjust your dose or share medication. Counterfeit Provigil may contain incorrect doses (e.g., dangerously high modafinil levels or none at all), leading to unpredictable health risks.

Interactions

Drug-Drug Interactions MAO Inhibitors (MAOIs): Combining Provigil with MAOIs (e.g., phenelzine, selegiline) can cause dangerous increases in blood pressure or serotonin syndrome. Avoid use within 14 days of stopping an MAOI. **Hormonal Contraceptives:** Provigil reduces the effectiveness of birth control pills, patches, or implants by speeding up their metabolism. Use non-hormonal contraception (e.g., condoms) during and for 1 month after treatment. **Blood Thinners (e.g., Warfarin):** Provigil may alter warfarin levels, increasing bleeding risks. Frequent monitoring of blood clotting (INR) is required. **Antidepressants (SSRIs/SNRIs):** May enhance stimulant effects, increasing anxiety or insomnia. Dose adjustments may be needed. **Cyclosporine & Certain Antivirals:** Provigil may lower cyclosporine or antiviral drug levels by accelerating their breakdown, reducing efficacy. **Drug-Food Interactions** **Caffeine:** Excessive caffeine (coffee, energy drinks) may worsen side effects like jitteriness or rapid heartbeat. **Grapefruit Juice:** May interfere with Provigil's metabolism, though evidence is limited. Consult your doctor before combining. **Drug-Supplement/Herb Interactions** **St. John's Wort:** Reduces Provigil's effectiveness by speeding its metabolism. Avoid concurrent use. **Stimulant Herbs (e.g., Guarana, Ephedra):** May amplify Provigil's side effects (e.g., high blood pressure, insomnia). **Impact of Interactions Reduced Effectiveness:** Drugs metabolized by CYP3A4 enzymes (e.g., some statins, antifungals) may become less effective. **Increased Toxicity:** Drugs metabolized by CYP2C19 enzymes (e.g., diazepam, omeprazole) may reach higher levels, raising overdose risks. **Critical Reminders** Inform your doctor about all medications, supplements, and herbs you use. **Counterfeit Alert:** Fake Provigil may contain undisclosed ingredients (e.g., amphetamines) with unpredictable, dangerous interactions.

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Other Details

Appearance Provigil tablets are round, white, and engraved with "PROVIGIL" on one side and the dosage strength (100 mg or 200 mg) on the reverse. Genuine tablets are packaged in blister packs with manufacturer branding. **Note:** Counterfeit versions may mimic this appearance, so always verify the source. **Storage** After Opening Keep tablets in their original blister pack or bottle to protect from moisture and light. Avoid transferring tablets to unmarked containers, as this increases the risk of misuse or confusion. **Disposal Guidelines** Do not flush or toss in household trash. As a controlled substance, follow local regulations for safe disposal. Utilize pharmacy take-back programs or authorized collection sites. **Lab Test Interference** Provigil may temporarily elevate liver enzyme levels (AST/ALT) in blood tests, potentially masking or mimicking liver issues. Inform your healthcare provider and lab personnel that you are taking modafinil before testing. **Additional Tips** Inspect packaging for signs of tampering (e.g., broken seals, misspelled words, faded ink). Avoid pill organizers unless necessary; retain original packaging to track expiration dates and lot numbers. If traveling, carry a prescription copy to avoid legal issues or suspicions of misuse. **Authenticity Verification** Purchase exclusively from licensed pharmacies with verifiable addresses. Check for a manufacturer's hologram or security seal on the packaging. Be wary of unusually low prices or unsolicited online offers, which often indicate counterfeit products.

References

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