



Patient Information

Provigil® Information Sheet©

- The recommended daily dose of Provigil is 200 mg to 400 mg per day.
- It comes in 100 mg and 200 mg tablets. 200 mg tablets are scored so they may be broken in half.
- It is probably best to start with 100 mg to 200 mg as a single daily dose soon after awakening in the morning.
- Absorption is more rapid on an empty stomach. Try to take it with at least 8 ounces of water, at least 30 minutes before you eat.
- Increase the dose in 100 mg increments (i.e. 100 mg → 200 mg → 300 mg → 400 mg) until you reach the desired dose. Occasional patients may require more than 400 mg per day.
- With the recommended once per day dosing, some patients will find that the stimulant effect wears off in late afternoon or early evening. In that case, adding a second dose at midday is helpful (e.g. 200 mg/200 mg, 200 mg/100 mg, or 300 mg/100 mg).
- There are essentially three ways to transition from other stimulants to Provigil:
 - 1) Stop current stimulant 48 hours or more before starting Provigil.
 - 2) Stop current stimulant and start Provigil the next day.
 - 3) Start Provigil and increase dose while slowly tapering off other stimulant.

There is no evidence that one method is best.

- Drug interactions: Definite drug interactions cannot be predicted. Provigil **may** interact with

There is no reason why Provigil and Ritalin (methylphenidate) or amphetamines cannot safely be taken simultaneously, so may patient may prefer tapering slowly from other stimulants after starting Provigil. This **may** reduce stimulant withdrawal effects.

No matter which method is used, you should expect to feel more fatigued and sleepy while withdrawing from Ritalin or amphetamines. This effect may last several weeks and the effectiveness of Provigil cannot be accurately judged until this withdrawal period has passed.

- Some patients are accustomed to getting a “boost” from other stimulants – a transient high. This is often missing with Provigil, since it is chemically very different from other stimulants. The lack of a “boost” does not mean it is not working. The key question is whether it helps you stay alert.
- Unlike some other stimulants (particularly amphetamines), Provigil has no anti-cataplexy effect. Cataplexy or other REM-related symptoms, such as sleep paralysis, may increase in frequency after switching to Provigil. If so, you may want to talk to your doctor about adding or increasing the dose of another medication to suppress cataplexy.

- Patients with severe kidney or liver impairment should talk to their doctor before taking Provigil.

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certain other drugs:

- 1) Blood levels of diazepam (Valium), phenytoin (Dilantin), propranolol (Inderal), warfarin (Coumadin), or similar drugs may be increased while taking Provigil.
- 2) In a small percentage of patients ($\leq 10\%$), Provigil may increase blood levels of some antidepressants (tricyclics and SSRIs), including Prozac.
- 3) **Provigil may reduce blood levels, and effectiveness, of birth control pills.** Women using birth control pills as their sole form of contraception should either talk to their gynecologist or family physician about this before starting Provigil, or use some other form of reliable birth control until they have a chance to talk to the doctor.
- 4) Blood levels of Theophylline, a drug sometimes used for asthma, or cyclosporine, a drug used in organ transplant patients, may be reduced while taking Provigil. Again, if you take these drugs, talk to the prescribing physician before starting Provigil.

- Provigil should not be taken during pregnancy.
- **Side effects:** The most commonly reported side effects are headache, nausea, and nervousness. These are usually mild and transient.
- *Rare cases of life-threatening rash have been reported with Provigil. If a rash occurs when initiating treatment, discontinue use of the medication immediately and contact this office or another healthcare professional.*
- *On rare occasions, psychiatric effects such as increased anxiety, mania and hallucinations have been reported in conjunction with Provigil use. Caution is advised in taking Provigil if there is a preexisting history of psychosis or mania.*

The Provigil Product Information sheet (PI), which is essentially the same as the Physician's Desk Reference (PDR) entry, may be found at the U.S. Food and Drug Administration web site (www.fda.gov). We can supply a printed copy of the PI for \$5.00.

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