Provigil (modafinil) - Drug Summary

Cephalon, Inc.

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Provigil
(modafinil)

THERAPEUTIC CLASS

Wakefulness-promoting agent

DEA CLASS

CIV

ADULT DOSAGE & INDICATIONS

Excessive Sleepiness

Associated w/ Narcolepsy/Obstructive Sleep Apnea/Shift Work Disorder:
200mg qd
Max: 400mg/day as a single dose

DOSING CONSIDERATIONS

Hepatic Impairment
Severe: 100mg qd

Elderly
Consider using lower doses

ADMINISTRATION

Oral route

Narcolepsy/Obstructive Sleep Apnea
Take as single dose in am

Shift Work Disorder
Take 1 hr prior to start of work shift

HOW SUPPLIED

Tab: 100mg, 200mg* *scored

WARNINGS/PRECAUTIONS

Not indicated as treatment for underlying obstruction in OSA; if continuous positive airway pressure (CPAP) is the treatment of choice, treat w/ CPAP for an adequate period of time prior to initiating and during treatment. Rare cases of serious or life-threatening rash, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash w/ eosinophilia and systemic symptoms (DRESS), reported; d/c at the 1st sign of rash, unless the rash is clearly not drug-related. Angioedema reported; d/c if angioedema or anaphylaxis occurs. Multiorgan hypersensitivity reactions reported; d/c if suspected. Level of wakefulness may not return to normal in patients w/ abnormal levels of sleepiness. Psychiatric adverse reactions reported; caution w/ history of psychosis, depression, or mania. Consider discontinuation if psychiatric symptoms develop in association w/ drug administration. May impair mental and/or physical abilities. Cardiovascular (CV) adverse reactions reported; not recommended in patients w/ a history of left ventricular hypertrophy (LVH) or in patients w/ mitral valve prolapse who have experienced mitral valve prolapse syndrome (eg, ischemic ECG changes, chest pain, arrhythmia) when previously receiving CNS stimulants. Caution w/ known CV disease (CVD). Caution in elderly. Potential for abuse.

ADVERSE REACTIONS

Headache, nausea, nervousness, anxiety, insomnia, rhinitis, diarrhea, back pain, dizziness, dyspepsia, anorexia, dry mouth, pharyngitis, chest pain, HTN.

DRUG INTERACTIONS

May reduce exposure of CYP3A4/5 substrates (eg, midazolam, triazolam); consider dose adjustment of these drugs. Effectiveness of steroidal contraceptives (eg, ethinyl estradiol) may be reduced when used w/ therapy and for 1 month after discontinuation of therapy; alternative or concomitant methods of contraception are recommended. May reduce levels of cyclosporine; consider dose adjustment for cyclosporine. May increase exposure of CYP2C19 substrates (eg, phenytoin, diazepam, propranolol). In individuals deficient in the CYP2D6 enzyme, levels of CYP2D6 substrates, which have ancillary routes of elimination through CYP2C19 (eg, TCAs, SSRIs) may be increased; dose adjustments of these drugs and other drugs that are substrates for CYP2C19 may be necessary. Consider more frequent monitoring of PT/INR w/ warfarin. Caution w/ MAOIs.

PREGNANCY AND LACTATION

Category C, caution in nursing.

MECHANISM OF ACTION

Wakefulness-promoting agent; has not been established. Binds to the dopamine transporter and inhibits dopamine reuptake.

PHARMACOKINETICS

Absorption: Readily absorbed. T_{max}=2-4 hrs, delayed by 1 hr (fed). **Distribution:** V_d=0.9L/kg; plasma protein binding (60%). **Metabolism:** Liver via hydrolytic deamidation, S-oxidation, aromatic ring hydroxylation, and glucuronide conjugation; CYP3A4. **Elimination:** Urine (80%) and feces (1%), <10% unchanged; $T_{1/2}$=15 hrs.

ASSESSMENT

Assess for hypersensitivity to the drug, history of psychosis, depression, mania, or LVH, mitral valve prolapse, other CVD, hepatic impairment, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for rash, SJS, TEN, DRESS, angioedema, anaphylaxis, multiorgan hypersensitivity reactions, psychiatric symptoms, CV events (especially in patients w/ a history of MI or unstable angina), and other adverse reactions. Monitor for signs of misuse or abuse. Monitor HR and BP. Frequently reassess degree of sleepiness. Monitor PT/INR frequently w/ warfarin.

PATIENT COUNSELING

Instruct to d/c use and notify physician immediately if allergic reactions and other adverse reactions (eg, chest pain, rash, depression, anxiety, signs of psychosis/mania) develop. Advise not to alter previous behavior w/ regard to potentially dangerous activities (eg, driving, operating machinery) or other activities requiring appropriate levels of wakefulness, until and unless treatment has been shown to produce levels of wakefulness that permit such activities. Inform that drug is not a replacement for sleep. Counsel patients that it may be critical that they continue to take their previously prescribed treatments (eg, patients w/ OSA receiving CPAP). Advise to notify physician if pregnancy occurs, if intending to become pregnant, or if breastfeeding. Caution regarding the potential increased risk of pregnancy when using steroidal contraceptives w/ therapy and for 1 month after discontinuation of therapy. Instruct to inform physician if taking/planning to take any prescription/OTC drugs, and to avoid alcohol.

STORAGE

20-25°C (68-77°F).

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