Taj Pharmaceuticals Ltd.

Modafinil

CAS No. : 68693-11-8

Molecular Formula C15H15NO2S

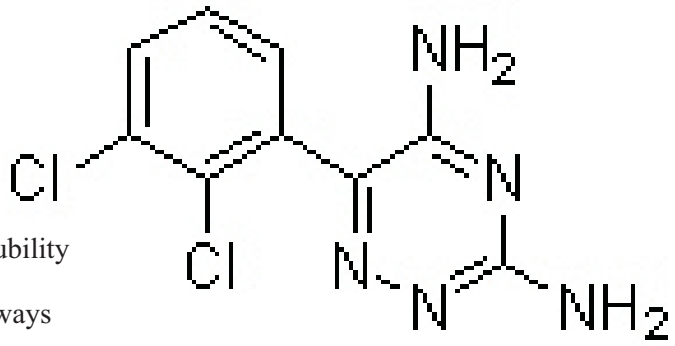
Molecular Weight 273.35

CAS Registry Number 68693-11-8

ATC code N06BA07
PubChem 4236
DrugBank APRD00534

Chemical data

Formula C15H15NO2S
Mol. mass 273.35
SMILES eMolecules & PubChem



Physical data

Melt. point 164–166 °C (327–331 °F)
Solubility in water 0.622 mg/mL (20 °C)
Pharmacokinetic data
Bioavailability Not determined due to the aqueous insolubility
Protein binding 60%
Metabolism Hepatic, including CYP3A4 and other pathways
Half life 10–12 hours
Excretion Urine (as metabolites)

Why is this medication prescribed?

Modafinil is used to treat excessive sleepiness caused by narcolepsy (a condition that causes excessive daytime sleepiness) or shift work sleep disorder (sleepiness during scheduled waking hours and difficulty falling asleep or staying asleep during scheduled sleeping hours in people who work at night or on rotating shifts). Modafinil is also used along with breathing devices or other treatments to prevent excessive sleepiness caused by obstructive sleep apnea/hypopnea syndrome (OSAHS; a sleep disorder in which the patient briefly stops breathing or breathes shallowly many times during sleep and therefore doesn't get enough restful sleep). Modafinil is in a class of medications called wakefulness promoting agents. It works by changing the amounts of certain natural substances in the area of the brain that controls sleep and wakefulness.

How should this medicine be used?

Modafinil comes as a tablet to take by mouth. It is usually taken once a day with or without food. If you are taking modafinil to treat narcolepsy or OSAHS, you will probably take it in the morning. If you are taking modafinil to treat shift work sleep disorder, you will probably take it 1 hour before the beginning of your work shift. Take modafinil at the same time every day. Do not change the time of day that you take modafinil without talking to your doctor. Talk to your doctor if your work shift does not begin at the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take modafinil exactly as directed.

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Modafinil may be habit-forming. Do not take a larger dose, take it more often, or take it for a longer period of time than prescribed by your doctor.

Modafinil may decrease your sleepiness, but it will not cure your sleep disorder. Continue to take modafinil even if you feel well-rested. Do not stop taking modafinil without talking to your doctor.

Modafinil should not be used in place of getting enough sleep. Follow your doctor's advice about good sleep habits. Continue to use any breathing devices or other treatments that your doctor has prescribed to treat your condition, especially if you have OSAHS.

USES

Modafinil decreases extreme sleepiness due to narcolepsy and other sleep disorders such as difficult/irregular breathing during sleep. It is also used to help you stay awake during work hours for people with work schedules that interfere with a normal sleep routine.

HOW TO USE

Take this medication by mouth with or without food, usually once daily in the morning or as directed by your doctor. If you are using modafinil for shift work sleep disorder, take this medication 1 hour before you start your work shift or as directed by your doctor. If you are using this for apnea , continue your other current treatment unless your doctor tells you to stop. Dosage is based on your medical condition and response to therapy. Use this medication exactly as prescribed to get the most benefit from it.

SIDE EFFECTS

Headache, nausea, nervousness, anxiety, dizziness, and difficulty sleeping may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

PRECAUTIONS

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: a certain heart problem (left ventricle thickening), a history of previous reaction (e.g., chest pain, irregular heartbeat) to stimulants.

MISSED DOSE

If you miss a dose, take 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. Missed doses should not be taken close to bedtime since it can interfere with your sleep.

STORAGE

Store at room temperature between 68-77 degrees F (20-25 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

DOSAGE

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.

The recommended dose of Modafinil is 200 mg given once a day.
For patients with narcolepsy and OSAHS, Modafinil should be taken as a single dose in the morning.
For patients with SWSD, Modafinil should be taken approximately 1 hour prior to the start of their work shift.

Doses up to 400 mg/day, given as a single dose, have been well tolerated, but there is no consistent evidence that this dose confers additional benefit beyond that of the 200 mg dose
Dosage adjustment should be considered for concomitant medications that are substrates for CYP3A4, such as triazolam and cyclosporineIn patients with severe hepatic impairment, the dose of Modafinil should be reduced to one-half of that recommended for patients with normal hepatic functionIn elderly patients, elimination of Modafinil and its metabolites may be reduced as a consequence of aging. Therefore, consideration should be given to the use of lower doses in this population

DRUG DESCRIPTION

Modafinilincreases the release of monoamines but also elevates hypothalamic histamine levels,[3] leading some researchers to consider Modafinil a "wakefulness promoting agent" rather than a classic amphetamine-like stimulantAlthough modafinil is thought to be effective in the treatment of Attention-Deficit Hyperactivity Disorder.

Modafinil is a white to off-white, crystalline powder that is practically insoluble in water and cyclohexane. It is sparingly to slightly soluble in methanol and acetone.modafinil following inactive ingredients: lactose, microcrystalline cellulose, pregelatinized starch, croscarmellose sodium, povidone, and magnesium stearate.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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