ArmodArmodafinil

PATIENT DATA SHEET

Armodafinil 150mg by Emcure Pharmaceuticals

Keep out of Reach of Children

Do not take Armodafinil if you have:

- an allergic reaction to Armodafinil
- cardiovascular disease
- recent myocardial infarction
- severe unstable angina

Not to be taken by children under the age of 18.

Do not take alcohol with Armodafinil.

Product name

Emcure Pharmaceuticals Armodafinil 150mg

Why is this medication prescribed?

Armodafinil 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). Armodafinil 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 does not get enough restful sleep). Armodafinil 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?

Armodafinil comes as a tablet to take by mouth. It is usually taken once a day. If you are taking armodafinil to treat narcolepsy or OSAHS, you will probably take it in the morning. If you are taking armodafinil to treat shift work sleep disorder, you will probably take it 1 hour before the start of your shift. Take armodafinil at around the same time every day. Do not change the time of day that you take armodafinil 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 our doctor or pharmacist to explain any part you do not understand. Take armodafinil exactly as directed.

Armodafinil 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.

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

Armodafinil 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.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

tell your doctor and pharmacist if you are allergic to armodafinil, modafinil (Provigil) or any other medications.

tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin); clomipramine (Anafranil); cyclosporine (Gengraf, Neoral, Sandimmune); diazepam (Valium); erythromycin (E.E.S., E-Mycin, Erythrocin); ketoconazole (Nizoral); omeprazole (Prilosec, in Zegerid); certain medications for seizures such as carbamazepine (Epitol, Equetro, Tegretol), phenobarbital, and phenytoin (Dilantin, Phenytek); midazolam; monoamine oxidase (MAO) inhibitors such as isocarboxazid (Marplan), phenelzine (Nardil), selegiline (Eldepryl, Emsam, Zelapar), and tranyleypromine (Parnate); propranolol (Inderal); rifampin (Rifadin, Rimactane, in Rifamate); and triazolam (Halcion). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with armodafinil, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.

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tell your doctor if you drink or have ever drunk large amounts of alcohol, use or have ever used street drugs or have overused prescription medications. Also tell your doctor if you have ever had chest pain, an irregular heartbeat, or other heart problems after taking a stimulant, and if you have or have ever had a heart attack; chest pain; high blood pressure; a mental illness such as depression, mania (frenzied, abnormally excited mood), or psychosis (difficulty thinking clearly, communicating, understanding reality, and behaving appropriately); or heart, liver, or kidney disease.

you should know that armodafinil may decrease the effectiveness of hormonal contraceptives (birth control pills, patches, rings, implants, injections, and intrauterine devices). Use another form of birth control while you are taking armodafinil and for 1 month after you stop taking it. Talk to your doctor about types of birth control that will work for you during and after your treatment with armodafinil.

tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking armodafinil, call your doctor.

f you are having surgery, including dental surgery, tell the doctor or dentist that you are taking armodafinil.

you should know that armodafinil may affect your judgment, thinking and movement, and may not completely relieve the sleepiness caused by your disorder. Do not drive a car or operate machinery until you know how this medication affects you. If you avoided driving and other dangerous activities because of your sleep disorder, do not start performing these activities again without talking to your doctor even if you feel more alert.

be aware that you should avoid drinking alcohol while you are taking this medication.

What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit and drinking grapefruit juice while taking this medicine.

What should I do if I forget a dose?

Skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

headache dizziness difficulty falling asleep or staying asleep difficulty concentrating or paying attention uncontrollable shaking of a part of the body numbness, burning, or tingling of the hands or feet nausea vomitina heartburn stomach pain constipation diarrhea loss of appetite thirst dry mouth sweating frequent urination

What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else take your medication. Selling or giving away armodafinil is against the law. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

MEDICINE SCHEDULE

Prescription Only Medicine

