

MEDICATION GUIDE

ARMODAFINIL (ar moe daf' i nil) TABLETS C-IV

What is the most important information I should know about armodafinil tablets?

Armodafinil tablet is a federal controlled substance (C-IV) because it can be abused or lead to dependence. Keep armodafinil in a safe place to prevent misuse and abuse. Selling or giving away armodafinil may harm others, and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

Armodafinil tablet may cause serious side effects including a serious rash or a serious allergic reaction that may affect parts of your body such as your liver or blood cells. Any of these may need to be treated in a hospital and may be life-threatening.

Stop taking armodafinil tablet and call your doctor right away or get emergency help if you have any of these symptoms:

- skin rash, hives, sores in your mouth, or your skin blisters and peels
- swelling of your face, eyes, lips, tongue, or throat
- trouble swallowing, breathing or hoarseness
- fever, shortness of breath, swelling of the legs, yellowing of the skin or whites of the eyes, or dark urine.

If you have a severe rash with armodafinil tablet, stopping the medicine may not keep the rash from becoming life-threatening or causing you to be permanently disabled or disfigured.

Armodafinil tablet is not approved for use in children for any medical condition.

It is not known if armodafinil tablet is safe and effective in children under the age of 18.

What is armodafinil tablet?

Armodafinil tablet is a prescription medicine used to improve wakefulness in adults who are very sleepy due to one of the following diagnosed sleep disorders:

- narcolepsy
- obstructive sleep apnea (OSA). Armodafinil tablet is used with other medical treatments for this sleep disorder. Armodafinil tablet does not take the place of using your CPAP machine or other treatments that your doctor has prescribed for this condition. It is important that you continue to use these treatments as prescribed by your doctor.
- shift work disorder (SWD)

Armodafinil tablet will not cure these sleep disorders. Armodafinil tablet may help the sleepiness caused by these conditions, but it may not stop all your sleepiness. Armodafinil tablet does not take the place of getting enough sleep. Follow your doctor's advice about good sleep habits and using other treatments.

Do not take armodafinil tablet:

- are allergic to any of its ingredients. See the end of this Medication Guide for a complete list

of ingredients in armodafinil tablet.

- have had a rash or allergic reaction to either armodafinil or modafinil (PROVIGIL[®]). These medicines are very similar.

Before you take armodafinil, tell your doctor about all of your medical conditions, including if you:

- have a history of mental health problems, including psychosis
- have heart problems or had a heart attack
- have high blood pressure. Your blood pressure may need to be checked more often while taking armodafinil tablet.
- have liver or kidney problems
- have a history of drug or alcohol abuse or addiction
- are pregnant or planning to become pregnant. It is not known if armodafinil tablet will harm your unborn baby.
- are breastfeeding. It is not known if armodafinil passes into your milk. Talk to your doctor about the best way to feed your baby if you take armodafinil tablet.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Armodafinil tablet and many other medicines can interact with each other, sometimes causing side effects. Armodafinil tablet may affect the way other medicines work, and other medicines may affect how armodafinil tablet works. Your dose of armodafinil tablet or certain other medicines may need to be changed.

Especially, tell your doctor if you use or take:

- a hormonal birth control method, such as birth control pills, shots, implants, patches, vaginal rings, and intrauterine devices (IUDs). Hormonal birth control methods may not work while you take armodafinil tablet. Women who use one of these methods of birth control may have a higher chance for getting pregnant while taking armodafinil tablet, and for 1 month after stopping armodafinil tablet. You should use effective birth control while taking armodafinil and for 1 month after your final dose. Talk to your doctor about birth control choices that are right for you while taking armodafinil tablet.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine. Your doctor or pharmacist will tell you if it is safe to take armodafinil tablet and other medicines together. Do not start any new medicines with armodafinil tablet unless your doctor has told you it is okay.

How should I take armodafinil tablet?

- Take armodafinil tablet exactly as prescribed by your doctor. Your doctor will prescribe the dose of armodafinil tablet that is right for you. Do not change your dose of armodafinil tablet without talking to your doctor.
- Your doctor will tell you the right time of day to take armodafinil tablet.
 - People with narcolepsy or OSA usually take armodafinil tablet one time each day in the morning.
 - People with SWD usually take armodafinil tablet about 1 hour before their work shift.
- Do not change the time of day you take armodafinil tablet unless you have talked to your

doctor. If you take armodafinil tablet too close to your bedtime, you may find it harder to go to sleep.

- You can take armodafinil tablet with or without food.
- If you take more than your prescribed dose or if you take an overdose of armodafinil tablet, call your doctor or poison control center right away.

Symptoms of an overdose of armodafinil tablet may include:

- Trouble sleeping
- Restlessness
- Confusion
- Feeling disoriented
- Feeling excited
- Hearing, seeing, feeling, or sensing things that are not really there (hallucinations)
- Nausea and diarrhea
- A fast or slow heartbeat
- Chest pain
- Increased blood pressure
- Anxiety
- Shortness of breath

What should I avoid while taking armodafinil tablet?

- Do not drive a car or do other dangerous activities until you know how armodafinil tablet affects you. People with sleep disorders should always be careful about doing things that could be dangerous. Do not change your daily habits until your doctor tells you it is okay.
- You should avoid drinking alcohol. It is not known how drinking alcohol will affect you when taking armodafinil tablet.

What are possible side effects of armodafinil tablet?

Armodafinil tablet may cause serious side effects. Stop taking armodafinil tablet and call your doctor right away or get emergency help if you get any of the following:

- **a serious rash or serious allergic reaction.** (See “**What is the most important information I should know about armodafinil tablet?**”)
- **mental (psychiatric) symptoms, including:**
 - depression
 - feeling anxious
 - hearing, seeing, feeling, or sensing things that are not really there (hallucinations)
 - an extreme increase in activity and talking (mania)
 - thoughts of suicide
 - aggressive behavior
 - other mental problems
- **symptoms of a heart problem,** including chest pain, abnormal heart beats, and trouble breathing.

The most common side effects of armodafinil tablets include:

- headache
- nausea
- dizziness
- trouble sleeping

These are not all the possible side effects of armodafinil tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store armodafinil tablet?

- Store armodafinil tablets at room temperature between 68° to 77° F (20° to 25° C).
- **Keep armodafinil tablets and all medicines out of the reach of children.**

General information about the safe and effective use of armodafinil tablet

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use armodafinil tablet for a condition for which it was not prescribed. Do not give armodafinil tablet to other people, even if they have the same symptoms that you have. It may harm them and is against the law.

You can ask your pharmacist or healthcare provider for information about armodafinil tablet that is written for health professionals. For more information, go to www.lupinpharmaceuticals.com or call 1-800-399-2561

What are the ingredients in armodafinil tablet?

Active ingredient: armodafinil

Inactive ingredients: lactose monohydrate, povidone, pregelatinised starch, sodium starch glycolate and sodium stearyl fumarate

This Medication Guide has been approved by the U.S. Food and Drug Administration

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