



Apotheken und Medikamente  
im Vergleich

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## **PATIENT INFORMATION**

### **WAKLERT Tablets**

**Generic name: armodafinil**

Read the Patient Information that comes with WAKLERT before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment.

#### **What is the most important information I should know about WAKLERT?**

**1. WAKLERT may cause you to have a serious rash or a serious allergic reaction. Stop WAKLERT and call your doctor right away or get emergency treatment if you have any of the following:**

- skin rash, hives, sores in your mouth, or your skin blisters and peels
- swelling of your face, eyes, lips, tongue, or throat
- trouble swallowing or breathing
- hoarse voice

**2. WAKLERT has not been studied in children under the age of 17. WAKLERT is not approved for children for any condition.**

#### **What is WAKLERT?**

WAKLERT is a prescription medicine used to improve awakeness in adults who are very sleepy due to one of the following diagnosed sleep problems:

- shift work sleep disorder (SWSD)
- obstructive sleep apnea/hypopnea syndrome (OSAHS). WAKLERT is used along with other medical treatments for this sleep problem. WAKLERT is not a replacement for your CPAP machine. It is important that you continue to use your CPAP machine while sleeping
- narcolepsy

You should be diagnosed with one of these sleep disorders before taking WAKLERT. Sleepiness can be a symptom of other medical conditions that need to be treated.

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

WAKLERT is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep WAKLERT in a safe place to prevent misuse and abuse. Selling or giving away WAKLERT 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.

#### **Who should not take WAKLERT?**

Do not take WAKLERT if you:

- are allergic to any of its ingredients. The active ingredient is armodafinil. See the end of this leaflet for a complete list of ingredients.

- have had a rash or allergic reaction to modafinil, the active ingredient in WAKLERT, because these medicines are very similar.

It is not known if WAKLERT works in or is safe for use in children under 17 years old.

### **What should I tell my doctor before starting WAKLERT?**

#### **Tell your doctor about all of your health conditions including, if you:**

- have a history of mental health problems
- have heart problems or had a heart attack
- have high blood pressure
- have liver or kidney problems
- have a history of drug or alcohol abuse or addiction
- have ever had a mental problem called psychosis
- are pregnant or planning to become pregnant. It is not known if WAKLERT may harm your unborn baby.
- are breastfeeding. It is not known if WAKLERT passes into your milk or if it can harm your baby.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. WAKLERT and many other medicines can interact with each other, sometimes causing side effects. WAKLERT may affect the way other medicines work, and other medicines may affect how WAKLERT works. Especially, tell your doctor if you use a hormonal birth control method. WAKLERT can affect hormonal birth control methods. Hormonal birth control methods include pills, shots, implants, patches, vaginal rings, and intrauterine devices (IUDs). Women who use hormonal birth control with WAKLERT may have a higher chance for getting pregnant while taking WAKLERT, and for one month after stopping WAKLERT. Talk to your doctor about birth control methods that are right for you while using WAKLERT.

Keep a list of all the medicines you take. Your doctor or pharmacist will tell you if it is safe to take WAKLERT and other medicines together. Do not take other medicines with WAKLERT unless your doctor has told you it is okay.

### **How should I take WAKLERT?**

Take WAKLERT exactly as prescribed by your doctor. Your doctor will prescribe the dose of WAKLERT that is right for you. Do not change your dose of WAKLERT without talking to your doctor. Do not take more WAKLERT than prescribed.

Your doctor will tell you the right time of day to take WAKLERT.

- Patients with narcolepsy or OSAHS usually take one dose of WAKLERT every day in the morning.
- Patients with SWSD usually take WAKLERT about 1 hour before their work shift. Do not change the time of day you take WAKLERT unless you have talked to your doctor. If you take WAKLERT too close to your bedtime, you may find it harder to go to sleep.
- you take more than your prescribed dose or overdose, call your doctor or poison control center right away.

### **What should I avoid while taking WAKLERT?**

- Do not drive a car or do other dangerous activities until you know how WAKLERT 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.
- Avoid drinking alcohol.

### **What are the possible side effects of WAKLERT?**

WAKLERT may cause serious side effects. Call your doctor or get emergency help if you have any of the including:

- a serious rash or serious allergic reaction. (See, “What is the most important information I should know about WAKLERT.”)
- mental (psychiatric) symptoms. Symptoms include depression, anxiety, hallucinations, mania, thoughts of suicide or other mental problems.
- heart problems including chest pain

The most common side effects of WAKLERT are headache, nausea, dizziness, and trouble sleeping.

WAKLERT may cause allergic reactions. If you get a rash, hives or other allergic reaction, stop taking WAKLERT and call your doctor right away.

If you have either of the problems listed below or any other serious side effects while taking WAKLERT stop taking WAKLERT and call your doctor or get emergency help:

- chest pain
- mental problems

Some effects of WAKLERT on the brain are the same as other medicines called “stimulants”. These effects may lead to abuse or dependence on WAKLERT. Before starting WAKLERT, tell your doctor if you have ever abused drugs, including other stimulant medicines.

Tell your doctor if you get any side effect that bothers you or that does not go away while taking WAKLERT.

These are not all the side effects of WAKLERT. For more information, ask your doctor or pharmacist.

### **How should I store WAKLERT?**

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