PrALERTEC®*

Modafinil
Tablets 100 mg

Guide for Patients and Caregivers

This material was developed by Teva Canada Innovation, as part of the risk minimization plan for ALERTEC®. This material is not intended for promotional use.

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WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ALERTEC®?

Read all the information in this booklet carefully before starting ALERTEC® and ask people who live with you to also read it. This is a summary and does not give all the information regarding ALERTEC®. Read the Patient Medication Information Leaflet that comes with each prescription for more extensive information.

This booklet and the Patient Medication Information Leaflet do not take the place of talking with your healthcare professional about your excessive sleepiness. Ask your healthcare professional about any questions or concerns you may have.

What is in this leaflet:

1. What is ALERTEC® and what is it used for?

ALERTEC® is a central nervous system (CNS) stimulant and contains the active ingredient modafinil. ALERTEC® is used to treat adults who are very sleepy due to excessive daytime sleepiness caused by one of the following conditions: obstructive sleep apnea (OSA), a breathing disorder during sleep, narcolepsy (uncontrollable, sudden attacks of sleep), or shift work disorder (SWD), a sleep disorder that happens to people who work long hours or irregular schedules, like nightshifts or rotating schedules.

ALERTEC® is not approved for use in children for any medical condition.

2. What you need to know before you take ALERTEC®

Who should not take ALERTEC®?

Do not take ALERTEC® if:

- You are allergic to modafinil, armodafinil or to any other ingredient in ALERTEC®.
- You have severe anxiety (feel very worried, nervous, or stressed) or are very agitated.
- You are pregnant or may become pregnant.

Information you need to tell your healthcare professional before you start taking ALERTEC®

Medications you are taking

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines as they can have an effect on each other.

- ALERTEC® can reduce the effects of certain hormonal birth control methods used to prevent pregnancy. These methods can include birth control pills, shots, implants, intrauterine devices (IUDs), or patches.
- If you are using a hormonal birth control method that includes birth control pills, shots, implants, intrauterine devices (IUDs), or patches, talk to your healthcare professional to find about the appropriate methods of contraception.

Consult the Patient Medication Information Leaflet for a list of medications that may interact with ALERTEC®.

Health conditions that you have

To help avoid side effects, talk to your healthcare professional about any health conditions you may have, including if:

- You have high blood pressure.
- You have or have had heart or blood vessel problems (e.g., coronary artery disease, heart attacks, unstable angina, and irregular heartbeat or rhythm).
- You have liver or kidney problems.
- You have or had a mental health problem.
- You have ever had a problem with substance use, including prescribed or illegal drugs, stimulants (e.g., methylphenidate, amphetamine, or cocaine) or alcohol.
- You have one of the following rare genetic conditions: galactose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption.
- You have had an allergic reaction to other medicines.
- You are over the age of 65 years old.
- You are drinking or plan to drink alcohol. Avoid consuming alcohol while taking ALERTEC®.

3. How does ALERTEC® work?

ALERTEC® belongs to a group of medicines called central nervous system (CNS) stimulants. The exact way that ALERTEC® works is not known. However, it is thought to stimulate your brain to promote mental and physical processes.

4. How do I take ALERTEC®?

Take ALERTEC® by mouth exactly as prescribed by your healthcare professional. Do not change your dose or the time of day you take ALERTEC® without talking to your healthcare professional.

Taking ALERTEC® in the evening or the late afternoon may prevent you from falling asleep at your usual bedtime, and should, therefore, be avoided. If you are unsure what to do, talk to your healthcare professional.

ALERTEC® does not take the place of getting enough sleep. Follow your healthcare professional's advice about good sleeping habits.

You may not feel like ALERTEC® is working right away. It may take an hour or so before you feel the effects.

5. What happens if I miss a dose of ALERTEC®?

If you forget or miss a dose of ALERTEC®, take it as soon as you remember it, unless it is close to the time of your next dose. If it is close to the time of your next dose, skip the missed dose and take the next dose at the usual scheduled time.

6. What should I do if I take too much ALERTEC®?

If you think you, or a person you are caring for, have taken too much ALERTEC®, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Overdose symptoms can cause:

- Trouble sleeping, feeling restless or agitated, feeling disoriented, feeling confused, feeling anxious, feeling excited, hearing, seeing, feeling or sensing things that are not really there (hallucination), nausea, diarrhea, fast or slow heartbeat, an increase in blood pressure, and chest pain.

7. What should I avoid while taking ALERTEC®?

- Avoid other dangerous activities until you know how ALERTEC® will affect your level of wakefulness.
- Avoid drinking alcohol while taking ALERTEC®.

8. What are the possible side effects from using ALERTEC®?

IMPORTANT

- ALERTEC® can cause some unwanted side effects, such as a serious rash or a serious allergic reaction. In severe cases, the allergic reaction may affect multiple organs, which can be potentially life-threatening.

Stop taking ALERTEC® and call your healthcare professional immediately or get emergency treatment if you experience any of the following:

- Severe skin rash, redness, hives or your skin blisters and/or peels, the skin inside of the lips, eyes, mouth, nasal passages or genitals blisters and/or peels
- Swelling of your face, eyes, lips, tongue or throat
- Trouble swallowing or breathing
- Hoarse voice
- Sudden wheeziness, chest pain, or chest tightness
- Fever, chills, headache, body aches, swollen glands, flu-like feeling, yellow skin or eyes

Most common side effects

The most common side effects reported with ALERTEC® are listed below. These are not all the possible side effects you may have when taking ALERTEC®. If you experience any side effects not listed here, tell your healthcare professional.

- Back pain
- Diarrhea
- Difficulty falling asleep
- Drowsiness
- Nervousness
- Sleepiness
- Stuffy nose
- Upset stomach

9. Other warnings you should know about

Monitoring and testing

Your healthcare professional will perform various tests, such as an electrocardiogram (ECG), to monitor your health before, during and after your treatment.

Pregnancy* and Breastfeeding

Before you start your treatment, you must take a pregnancy test and have a negative pregnancy result at least one week prior to starting ALERTEC®. It is recommended that you take pregnancy tests throughout your treatment to allow the early detection of pregnancy.

Do not take ALERTEC® if:

- You are pregnant, as ALERTEC® can harm your unborn baby.
- You are breastfeeding or plan to breastfeed, as ALERTEC® can be passed into breast milk.

*** If you get pregnant or think you are pregnant while taking ALERTEC®, or if you get pregnant within two months after stopping ALERTEC®, tell your healthcare professional right away.**

Taking ALERTEC® can cause the following:

- **Abnormal heart beats** (arrhythmia)
- **High blood pressure** (hypertension)
- **Lack of blood flow to the heart which can lead to a heart attack** (myocardial ischemia): You are more likely to develop myocardial ischemia if you have coronary artery disease, have had a recent heart attack, or have unstable angina (not enough oxygen to the heart muscle).
- **Stroke:** (bleeding or blood clot in the brain).
- Worsening of **emotional or behaviour problems**, loss of contact with reality (psychotic episodes), overexcitement or feeling extreme happiness (mania), delusions, hallucinations, suicidal thoughts and aggression. If you have experienced mental health issues in the past, you may be more likely to develop mental and behavioral changes.

Consult the Patient Medication Information Leaflet for a list of **serious side effects and what you can do about them.**

Abuse and misuse

ALERTEC® has the potential for you to become reliant (dependent) after long-term use, especially if you have a history of substance abuse or a history of mental health problems. Your healthcare professional will monitor your risk for these behaviours. However, if you notice any signs of abuse or misuse (e.g., if you have a craving for ALERTEC®), tell your healthcare professional right away.

Sleepiness

ALERTEC® may help to treat your sleepiness, but it may not stop all of your sleepiness. Discuss your level of sleepiness with your healthcare professional during each visit.

Some people may experience side effects other than those listed here. Check with your healthcare professional if you notice any symptom that worries you, or any unexpected effect, while you are taking this medication.

Driving and using machines

ALERTEC® can cause over-stimulation and overconfidence. Before you drive or do tasks that require special attention, wait until you are certain that ALERTEC® does not affect your ability to engage in these activities.

10. What are the ingredients in ALERTEC® and what does it look like?

Each white to off-white tablet, marked with "100" on one side, contains 100 mg of modafinil.

ALERTEC® also contains the non-medicinal ingredient lactose.

11. How should I store ALERTEC®?

Store this medication at room temperature and keep it out of the reach and sight of children.

Do not dispose of medications in wastewater (e.g., down the sink or in the toilet) or in household garbage. Ask your pharmacist how to dispose of medications that are no longer needed or have expired.

12. How do I report suspected side effects?

It is important to report suspected side effects of all medications. A report should include as much information as possible on the medicine/s you are taking (including when you took the medicine, lot numbers and expiry dates), and the adverse event that occurred (when it occurred, what occurred, how was it treated). Report the adverse reaction as soon as possible either to Teva Canada Limited at 1-866-530-6065, by fax at 1-416-335-4472 or to Health Canada.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

If you want more information about ALERTEC®:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website at https://pdf.hres.ca/dpd_pm/00071543.PDF, or by calling 1-855-223-6838.

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