

Pr **ALERTEC**^{®*}

Modafinil

Tablets 100 mg

Central Nervous System Stimulant

Guide for Patients and Caregivers

ALERTEC[®] is manufactured by:
Teva Canada Limited
Toronto, Ontario
M1B 2K9

ALERTEC[®] is distributed by:
Teva Canada Innovation
Montréal, Quebec
H2Z 1S8

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

ALERTEC is used to treat adults who are very sleepy due to one of the following medical conditions:

- **Narcolepsy:** People who have this condition experience sudden attacks of sleep that cannot be controlled.
- **Obstructive Sleep Apnea (OSA):** People with this condition have breathing problems during sleep. You should talk with your healthcare professional about treatments for OSA before you start taking ALERTEC. ALERTEC does not take the place of other treatments that your healthcare professional has prescribed for OSA. It is important that you continue to use these treatments as prescribed by your healthcare professional.
- **Shift Work Disorder (SWD):** People with this condition experience very strong feelings of sleepiness when they work in shifts or irregular schedules outside the normal sleep period. ALERTEC may help to reduce your sleepiness caused by SWD, but it may not help you to do your work better than you did before taking ALERTEC.

ALERTEC is not approved for use in children for any medical condition. ALERTEC should not be used in patients who are pregnant or plan to become pregnant.

IMPORTANT

ALERTEC can cause some unwanted side effects. ALERTEC may cause you to have a serious rash or a serious allergic reaction. Stop ALERTEC and call your doctor immediately or get emergency treatment if you experience any of the below:

- 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

This booklet will help you learn more about ALERTEC.

Additionally you can get more information by consulting:

- A toll-free number 1-855-223-6838 to call if you have questions about ALERTEC.
- A Patient Information Leaflet (found inside your medication package) that gives important safety information.

Read this booklet carefully before starting ALERTEC. Also, read the Patient Information Leaflet that comes with each prescription for ALERTEC as it contains more extensive information.

Ask the people who live with you to read this information. This booklet and the Patient Information Leaflet do not take the place of talking with your doctor about your excessive sleepiness. Ask your doctor or healthcare professional about any questions you may have. Talk with them about any concerns you have.

What is ALERTEC used for?

ALERTEC is used to treat adults who are very sleepy due to obstructive sleep apnea (breathing disorder during sleep), narcolepsy (uncontrollable, sudden attacks of sleep), or shift work sleep disorder.

Who should not take ALERTEC?

Do not take ALERTEC if you:

- Are very agitated or have severe anxiety (feel very worried, nervous or stressed).
- Are allergic to modafinil or to any of the non-medicinal ingredients in ALERTEC. See Patient Information Leaflet for a complete list of ingredients in ALERTEC.
- Are under the age of 18.
- Are pregnant or may become pregnant.

ALERTEC should not be used for the treatment of normal fatigue states. ALERTEC does not take the place of getting enough sleep.

There is no evidence that normal levels of attention can be increased by ALERTEC.

How should I use ALERTEC?

- Take ALERTEC exactly as prescribed by your healthcare professional. Do not change your dose of ALERTEC without talking to your healthcare professional.
- Your healthcare professional will tell you the right time of day to take ALERTEC. Do not change the time of day you take ALERTEC unless you have talked to your healthcare professional.
- ALERTEC starts to work slowly. It may take an hour or so before you feel the effects.
- It is important to take this medication exactly as prescribed by your doctor. If you forget to take your medication, take it when you remember, unless it is close to the time of your next dose. Taking your medication in the evening or the late afternoon may prevent you from falling asleep at your usual bedtime, and should, therefore, be avoided. If you take ALERTEC too close to your bedtime, you may find it harder to go to sleep. If you are not sure what to do after missing a dose, contact your doctor or pharmacist for advice.
- Your doctor may request an electrocardiogram (ECG) before starting you on ALERTEC. You may also have your blood pressure and heart rate monitored while you are taking ALERTEC.
- Before you start ALERTEC, you should have a negative pregnancy test within a week. It is recommended that you repeat pregnancy test as often as you or your doctor feel necessary to do so.
- 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.

What does ALERTEC look like?

- Each white to off-white, capsule shaped tablet, marked with “100” on one side, contains modafinil 100 mg.



Drugs that interact with ALERTEC

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. Consult the Patient Information Leaflet for a list of medications that may interact with ALERTEC.

Other warnings you should know about:

- Women who use certain types of birth control may have a higher chance of getting pregnant while taking ALERTEC, and for two months after stopping ALERTEC. Talk to your healthcare professional about birth control methods that are right for you while using ALERTEC.
- Your healthcare professional may request a test for your heart called an electrocardiogram (ECG) before you start taking ALERTEC. You may also have your blood pressure and heart rate monitored while you are taking ALERTEC.
- ALERTEC does not take the place of getting enough sleep. Follow your healthcare professional's advice about good sleep habits.
- There is no proof that ALERTEC will help to increase your usual level of attention.
- ALERTEC may help to treat your strong feelings of sleepiness, but it may not stop all your sleepiness. Discuss your level of sleepiness with your healthcare professional at each visit.
- Do not drive a car or do other dangerous activities until you know how ALERTEC affects you. People with sleep disorders should always be careful about doing things that could be dangerous. Do not change your daily habits without talking to your healthcare professional.
- Avoid drinking alcohol.
- While you are taking ALERTEC, continue your other prescribed treatments. For example, if you have breathing problems during sleep, it is very important for you to continue the treatment that you used before starting to take ALERTEC.
- ALERTEC can be abused or lead to dependence.

What are the possible side effects of ALERTEC?

The most common side effects reported with ALERTEC are listed below. If you are concerned about side effects or experience any side effects not listed here, contact your doctor. Contact your doctor if you experience these side effects and they are severe or bothersome.

- Anxiety
- Back pain
- Diarrhea
- Dizziness
- Headache
- Hypertension
- Nausea
- Nervousness
- Difficulty falling asleep
- Sleepiness or drowsiness
- Stuffy nose
- Upset stomach

ALERTEC may cause serious side effects. Consult the Patient Information Leaflet for a list of **serious side effects** and for instructions about what to do in case you experience them:

- **Heart problems:** fast and/or abnormal heart beat and chest pain
- **Mental problems:** signs of depression, anxiety, hallucinations, thoughts of suicide and aggression, and extreme increase in activity and talking (mania).
- **Allergic reaction:** rash; hives; swelling of the face, lips, tongue or throat; difficulty swallowing or breathing; hoarse voice
- **Serious skin rash:** hives, sores in the mouth, blistering and peeling skin
- **Reproductive function:** Alertec may harm your unborn baby.

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

What happens if I miss a dose of ALERTEC?

If you forget to take your medication, take it when you remember, unless it is close to the time of your next dose. Taking your medication in the evening or the late afternoon may prevent you from falling asleep at your usual bedtime, and should, therefore, be avoided. If you take ALERTEC too close to your bedtime, you may find it harder to go to sleep.

What should I do if I take an overdose of ALERTEC?

Seek emergency medical attention or contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Overdose symptoms may include trouble sleeping, restlessness, disorientation, confusion, agitation, anxiety, excitation, hallucination, nausea, vomiting, diarrhea, an increase or decrease in heart rate, an increase in blood pressure and chest pain.

What should I avoid while taking ALERTEC?

ALERTEC affects the central nervous system. ALERTEC may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be alert. Avoid other dangerous activities until you know how ALERTEC will affect your level of wakefulness.

Avoid drinking alcohol while taking ALERTEC.

ALERTEC can be abused or lead to dependence.

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 occurred, what occurred, how was it treated). Report the adverse reaction as soon as possible either to Teva Canada Limited at 1-800-268-4127 option 3 (English), 1-877-777-9117 (French), Telefax: 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 (<http://hc-sc.gc.ca/index-eng.php>), the manufacturer's website (<http://www.tevacanadainnovation.ca>), or by calling 1-855-223-6838.

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