Pr ALERTEC®*

Modafinil
Tablets 100 mg

Central Nervous System Stimulant

Guide for Patients & Caregivers

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

ALERTEC® is distributed by:
Shire Canada Inc.
Saint Laurent, Québec
H4S 2C9

* ALERTEC® is a registered trade-mark used under licence from Cephalon, Inc., a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd.

What is the most important information I should know about ALERTEC®?

Your doctor has prescribed ALERTEC® for you to treat excessive sleepiness caused by obstructive sleep apnea (OSA, breathing disorder during sleep), narcolepsy (uncontrollable, brief episodes of sleep), or shift work sleep disorder (SWD). In narcolepsy, ALERTEC® has no effect on cataplexy (sudden loss of muscular tone). In OSA, ALERTEC® should be used along with successful standard medical treatments for the breathing disorder. In SWD, ALERTEC® is intended to reduce your sleepiness, but may not improve your work performance. ALERTEC® is not approved for use in children.

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®, as explained below

- What is ALERTEC®?
- Who should not take ALERTEC®?
- How should I use ALERTEC®?
- What form does ALERTEC® come in?
- What should I discuss with my Health Care Professional before taking ALERTEC®?
- What are the possible side effects of ALERTEC®?
- What happens if I miss a dose of ALERTEC®?
- What happens if I overdose ALERTEC®?
- What should I avoid while taking ALERTEC®?
- How do I report suspected side effects?
- Where can I get more information on 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 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 and possibly updated 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 pharmacist any questions you may have. Talk with them about any concerns you have.

What is ALERTEC®?

ALERTEC® is used to treat excessive sleepiness caused by sleep apnea (breathing disorder during sleep), narcolepsy (uncontrollable, brief episodes of sleep), or shift work sleep disorder.

Who should not take ALERTEC®?

Do not take ALERTEC® if you:

- Are already agitated or have severe anxiety.
- Have had a rash or allergic reaction to either modafinil (ALERTEC®) or armodafinil (similar active ingredient in a product sold in the U.S.) or to any of its inactive ingredients or components of the container. See Patient Information Leaflet for a complete list of ingredients in ALERTEC®.
- Are under the age of 18.

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®?

- Patients with narcolepsy usually take ALERTEC® as one (1) to two (2) tablets in the morning and one (1) to two (2) tablets at noon. Your doctor will try to adjust the dose to coincide with the periods of greatest sleepiness during the day. The second dose should normally be taken at noon or early in the afternoon to prevent difficulties falling asleep at bedtime. ALERTEC® starts to work slowly. It may take an hour or so before you feel the effects.
- For adults with obstructive sleep apnea, the usual adult daily dose of ALERTEC® is 200 mg (two tablets) taken as a single dose in the morning.
- Adults with shift work disorder should take 200 mg (two tablets) once daily, approximately 1 hour before the start of the work shift.
- It is important to take this medication exactly as prescribed by your doctor. If you miss a dose, take it as soon as possible and continue with your regular schedule. If it is almost time for your next dose, skip the missed dose and continue with your regular dosing schedule. Do not take a double dose to make up for a missed one. If you are not sure what to do after missing a dose, contact your doctor or pharmacist for advice.
- Avoid taking the medication in the late afternoon or evening, as it may prevent falling asleep at your normal bedtime.
- 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®.
- 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 form does ALERTEC® come in?

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

What should I discuss with my Health Care Professional before taking ALERTEC®?

- **ALERTEC®** may affect the way other medicines work, and other medicines may affect how ALERTEC® works. Your doctor will decide if you can take **ALERTEC®** with your other medicines.
- Tell your doctor if you have or had any of these other conditions:
    - Angina (chest pain); cirrhosis or other liver problem; kidney problems; mental problem; a heart muscle or valve disorder such as mitral valve prolapse; a history of drug addiction; high blood pressure; if you take blood pressure medications; or if you have recently had a heart attack or other heart problems.
- Skin rashes serious enough to require hospitalization have occurred in people using ALERTEC®. These rashes usually occurred within 1 to 5 weeks after the first dose.
- Stop taking ALERTEC® and call your doctor at the first sign of any skin rash, no matter how minor you think it might be.
- It is not known whether ALERTEC® will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant while using this medication.
- Talk to your doctor or pharmacist if you are pregnant, breast feeding or planning to become pregnant. There is very limited information on the safety of ALERTEC® in these conditions. Therefore, ALERTEC® is not recommended during pregnancy and breast feeding.
- Women who use hormonal contraceptives such as birth control pills, shots, implants, intrauterine devices (IUDs), or patches, may have a higher chance for getting pregnant while taking ALERTEC®, and for one month after stopping ALERTEC®. Talk to your doctor about birth control methods that are right for you while using ALERTEC®.
- Discuss your level of sleepiness with your doctor at each visit.
- Do not give ALERTEC® to anyone younger than 18 years old.

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, discuss the risks and benefits of this medication with your doctor. Contact your doctor if you experience these side effects and they are severe or bothersome.

- Anxiety
- Back pain
- Diarrhea
- Dizziness
- Headache
- Hypertension
- Increased heart rate or palpitations (fast and/or abnormal heart beat)
- Nausea
- Nervousness
- Difficulty falling asleep
- Somnolence
- Stuffy nose
- Upset stomach

These side effects could lead to serious problems if you do not check with your doctor or seek medical attention. Check with your doctor as soon as possible if any of the following side effects occur:

- Agitation
- Dizziness or fainting
- Mood swings
- Signs of liver problems (such as yellow eyes or skin, abdominal pain, darkened urine)
- Skin rash

ALERTEC® may cause serious adverse effects. Stop taking ALERTEC® and seek immediate medical attention if any of the following occur:

- Heart problems including chest pain
- Mental problems, including signs of depression (such as feeling sad, losing interest in things you used to enjoy, weight changes, changes in sleep habits, feelings of guilt or worthlessness, thoughts of harming oneself), anxiety, hallucinations, mania thoughts of suicide and aggression
- Signs of allergic reaction (such as swelling of face, eyes, lips, tongue; difficulty swallowing or breathing; hoarseness; chest tightness)
- Signs of serious skin reaction (blistering rash with fever, sores in mouth, peeling skin)

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®?

Take the missed dose as soon as you remember, but avoid taking the medication if you do not plan to be awake for several hours. If it is close to your normal bedtime hour, you may need to skip the missed dose and wait until the next day to take the medicine again.

Talk with your doctor about what to do if you miss a dose of ALERTEC®. Do not take extra medicine to make up the missed dose.

What happens if I overdose with 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 insomnia, 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 and can be fatal either alone or in combination with other drugs.

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®.

Some effects of ALERTEC® on the brain are similar to, but less than, other medications called "stimulants" that may be associated with the potential for abuse or misuse.

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 or to Health Canada.

Identifying marketed health product-related adverse reactions depends on healthcare professionals and consumers reporting them. Any case of serious or unexpected adverse reactions in patients receiving ALERTEC® should be reported to the manufacturer (see the box below) or to Health Canada.

Teva Canada Limited
1-800-268-4127 ext. 5005 (English), 1-877-777-9117 (French), Telefax: 1-416-335-4472

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following three ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the Adverse Reaction Reporting section.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

Where can I get more information on ALERTEC®?

If you have any further questions on the use of ALERTEC®, ask your doctor or pharmacist, or call Teva Canada Innovation at: 1-855-223-6838.

This document, as well as the full product monograph (prepared for health professionals) can be found at the following web address: http://www.tevacanadainnovation.ca

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