

PART III: CONSUMER INFORMATION
ALERTEC®*
(modafinil tablets)

This leaflet is part III of a three-part "Product Monograph" published when ALERTEC was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ALERTEC. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

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

ALERTEC may cause you to have a serious rash or a serious allergic reaction. Stop ALERTEC 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.

ALERTEC is not approved for use in children.

What the medication is used for:

ALERTEC is intended to relieve the excessive sleepiness due to medical conditions called narcolepsy (uncontrollable, brief episodes of sleep), obstructive sleep apnea (OSA) (breathing disorder during sleep) and circadian rhythm sleep disorder, shift work type (shift work 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.

What it does:

As with many medicines affecting the brain, the mechanism of action of this medicine is not entirely known.

When it should not be used:

You should not take this medicine if you are already agitated or have severe anxiety.

You should not take this medication if you are allergic to modafinil, armodafinil (similar active ingredient in a product sold in the U.S.) or to any of the non-medicinal ingredients in it (see the paragraphs entitled "What the medicinal ingredient is" and "What the important nonmedicinal ingredients are" below).

The safety and efficacy of ALERTEC in children under the age of 18 has not been established and therefore it should not be used in pediatric patients.

What the medicinal ingredient is:

Modafinil

What the important nonmedicinal ingredients are:

Lactose monohydrate, maize starch, magnesium monosilicate, sodium croscarmellose, polyvidone, magnesium stearate, and talc.

What dosage forms it comes in:

Each tablet contains 100mg of an active ingredient called modafinil.

WARNINGS AND PRECAUTIONS

Serious skin rashes have been reported in patients using ALERTEC. (See "What is the most important information I should know about ALERTEC?")

BEFORE you use ALERTEC talk to your doctor or pharmacist if:

- you are using a hormonal birth control method. 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.
- you have high blood pressure, you have heart problems, or have had a heart attack.
- you have liver or kidney problems.
- you have or had a mental problem.
- you have abused medicines called "stimulants" or street drugs.
- 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.
- you are taking other medicines, including prescription and non-prescription medicines, vitamins and herbal supplements. ALERTEC and many other medicines can interact with each other causing side effects. ALERTEC may affect the way other medicines work, and other medicines may affect how ALERTEC works. Keep a list of all the medicines you take. Your doctor will decide if you can take ALERTEC with your other medicines.

Special concerns

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.

ALERTEC may help treat the excessive sleepiness in most narcoleptic, OSA and SWD patients, but it may not stop all your sleepiness. Discuss your level of sleepiness with your doctor at each visit.

You should avoid driving a car, operating hazardous machinery or engage in any other potentially dangerous activity until you are certain of how ALERTEC affects your sleepiness.

Avoid drinking alcohol.

It may be critical that you continue to take your previously prescribed treatments (e.g., patients with breathing disorder during sleep must also receive a standard medical treatment for the breathing disorder while taking ALERTEC). ALERTEC is not a replacement for your CPAP machine. It is important that you continue to use your CPAP machine while sleeping.

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.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with ALERTEC include: antipyrine, clomipramine, cyclosporine, dextroamphetamine, diazepam, methylphenidate, monoamine oxidase (MAO) inhibitors, oral contraceptives, phenytoin, propranolol, selective serotonin reuptake inhibitors, S-mephenytoin, triazolam, tricyclic antidepressant, warfarin.

ALERTEC and many other medicines, including prescription and non-prescription medicines, dietary supplements, and herbal remedies, can interact with each other causing side effects. ALERTEC may affect the way other medicines work, and other medicines may affect how ALERTEC works. Keep a list of all the medicines you take. Your doctor will decide if you can take ALERTEC with your other medicines.

PROPER USE OF THIS MEDICATION

Usual dose:

Take as directed by your doctor.

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.

It is not recommended to take more than 4 tablets a day (400mg). Do not take more tablets or take more often than you are told.

Patients with OSA usually take ALERTEC as two (2) tablets in the morning.

Patients with SWD usually take ALERTEC as two (2) tablets about 1 hour before their work shift.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms. Make sure you take your medicine with you to show the doctor.

An overdose can cause 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.

Missed Dose:

If you forget to take your medication, take it when you remember, unless it is close to the time for the 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects reported with this medicine are:

- Headache
- Difficulty falling asleep
- Nervousness
- Nausea
- Stuffy nose
- Diarrhea
- Back pain
- Anxiety
- Upset stomach
- Dizziness
- Somnolence
- Hypertension
- Tachycardia (abnormal heart beat)

These side effects tend to disappear after a few days or after a reduction of the dosage. Reaching the maximum daily dosage progressively over several days may prevent these side effects.

ALERTEC may cause serious side effects. Call your doctor or get emergency help if you experience any of the following infrequent side effects:

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate medical emergency assistance
		Only if severe	In all cases	
Uncommon	Heart problems including chest pain			√
	Mental problems including depression, anxiety, hallucinations, mania, thoughts of suicide, aggression			√
	Serious skin rash			√
	Allergic reaction			√

This is not a complete list of side effects. For any unexpected effects while taking ALERTEC, contact your doctor or pharmacist.

HOW TO STORE IT

This medicine should be stored at room temperatures between 15° and 30°C. If the medication has expired (the expiry date appears on the label of the prescription and/or the treatment pack) throw away your tablets.

Keep these tablets in a safe place, out of reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

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

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be provided by contacting the distributor, Shire Canada Inc. at: 1-800-268-2772

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