

MEDICATION GUIDE
RESTORIL™ (*res-tə-ril*)
(temazepam) Capsules, C-IV

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

- **RESTORIL is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma and death.**
- After taking RESTORIL, you may get up out of bed while not being fully awake and do an activity that you do not know you are doing. The next morning, you may not remember that you did anything during the night. You have a higher chance for doing these activities if you drink alcohol or take other medicines that make you sleepy with RESTORIL. Reported activities include:
 - driving a car (“sleep-driving”)
 - making and eating food
 - talking on the phone
 - having sex
 - sleep-walking

Call your healthcare provider right away if you find out that you have done any of the above activities after taking RESTORIL.

- Do not take RESTORIL unless you are able to stay in bed a full night (7 to 8 hours) before you must be active again.
- Do not take more RESTORIL than prescribed.

What is RESTORIL?

- RESTORIL is a prescription sleep medicine. RESTORIL is used in adults for the short-term (usually 7 to 10 days) treatment of a sleep problem called insomnia. Symptoms of insomnia include trouble falling asleep and waking up often during the night.
- **RESTORIL is a federal controlled substance (C-IV) because it can be abused or lead to dependence.** Keep RESTORIL in a safe place to prevent misuse and abuse. Selling or giving away RESTORIL may harm others, and is against the law. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- It is not known if RESTORIL is safe and effective in children.
- It is not known if RESTORIL is safe and effective for use longer than 2 weeks.

Do not take RESTORIL if you:

- are allergic to temazepam or any of the ingredients in RESTORIL. See the end of this Medication Guide for a complete list of ingredients in RESTORIL.

Before you take RESTORIL, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of depression, mental illness or, suicidal thoughts
- have a history of drug or alcohol abuse or addiction
- have lung disease or breathing problems
- are pregnant or plan to become pregnant. RESTORIL may cause birth defects or harm your unborn baby.
- are breastfeeding, or plan to breastfeed. RESTORIL may pass through your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take RESTORIL.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking RESTORIL with certain other medicines can cause side effects or affect how well RESTORIL or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

Do not take RESTORIL with other medicines that can make you sleepy unless your healthcare provider tells you to.

How should I take RESTORIL?

- **See “What is the most important information I should know about RESTORIL?”**
- Take RESTORIL exactly as your healthcare providers tell you to take it. Take RESTORIL right before you get into bed.
- Do not take RESTORIL unless you are able to get a full night’s sleep before you must be active again.
- If you take too much RESTORIL or overdose, get emergency treatment right away.

What should I avoid while taking RESTORIL?

- Do not drive, operate machinery, do other dangerous activities or do anything that needs you to be alert until you know how RESTORIL affects you.
- You should not drink alcohol while you are taking RESTORIL.

What are the possible side effects of RESTORIL?

RESTORIL may cause serious side effects, including:

- **See “What is the most important information I should know about RESTORIL?”**
- **Withdrawal symptoms.** You may have withdrawal symptoms if you stop taking RESTORIL suddenly. Withdrawal symptoms can be serious and include seizures shakiness, stomach and muscle cramps, vomiting and sweating. Mild withdrawal symptoms include a depressed mood and trouble sleeping. Talk to your healthcare provider about slowly stopping RESTORIL to avoid withdrawal symptoms.
- **Abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts.
- **Abuse and dependence.** Taking RESTORIL can cause physical and psychological dependence. Physical and psychological dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.
- **Severe allergic reactions.** Symptoms include swelling of the tongue or throat, trouble breathing, and nausea and vomiting. Get emergency medical help right away if you have these symptoms after taking RESTORIL.

The most common side effects of RESTORIL include:

- drowsiness
- headache
- tiredness
- nervousness
- dizziness
- nausea

You may still feel drowsy the next day after taking RESTORIL. **Do not drive or do other dangerous activities after taking RESTORIL until you feel fully awake.**

These are not all the possible side effects of RESTORIL. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store RESTORIL?

- Store RESTORIL between 68°F to 77°F (20°C to 25°C).
- **Keep RESTORIL and all medicines out of the reach of children.**

General information about the safe and effective use of RESTORIL.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RESTORIL for a condition for which it was not prescribed. Do not give RESTORIL to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about RESTORIL that is written for healthcare professionals.

What are the ingredients in RESTORIL?

Active Ingredient: temazepam

Inactive Ingredients: gelatin, lactose, magnesium stearate, red iron oxide, titanium dioxide

Manufactured by SpecGx LLC
Webster Groves, MO 63119

If you would like more information, call Mallinckrodt Inc. at 1-800-778-7898 or visit www.mallinckrodt.com.

This Medication Guide has been approved by the U.S. Food and Drug Administration

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Revised: September 2017
L20R02