

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 (CNS) depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma and death.** Get emergency help right away if any of the following happens:
 - shallow or slowed breathing
 - breathing stops (which may lead to the heart stopping)
 - excessive sleepiness (sedation)
- Do not drive or operate heavy machinery until you know how taking RESTORIL and opioids affects you.
 - **Risk of abuse, misuse, and addiction.** There is a risk of abuse, misuse, and addiction with benzodiazepines including RESTORIL which can lead to overdose and serious side effects including coma and death.
 - **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including RESTORIL.** These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. **Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these serious side effects.**
 - **You can develop an addiction even if you take RESTORIL as prescribed by your healthcare provider.**
 - **Take RESTORIL exactly as your healthcare provider prescribed.**
 - Do not share your RESTORIL with other people.
 - Keep RESTORIL in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** RESTORIL can cause physical dependence and withdrawal reactions.
 - **Do not suddenly stop taking RESTORIL.** Stopping RESTORIL suddenly can cause serious and life-threatening side effects, including, unusual movements, responses, or expressions, seizures, sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. **Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these symptoms.**
 - **Some people who suddenly stop benzodiazepines have symptoms that can last for several weeks to more than 12 months,** including, anxiety, trouble remembering, learning, or concentrating, depression, problems sleeping, feeling like insects are crawling under your skin, weakness, shaking, muscle twitching, burning or prickling feeling in your hands, arms, legs or feet, and ringing in your ears.
 - Physical dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical dependence and drug addiction.
 - Do not take more RESTORIL than prescribed or take RESTORIL for longer than prescribed.
- 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.

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 contains temazepam that 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.
 - Taking RESTORIL late in pregnancy may cause your baby to have symptoms of sedation (breathing problems, sluggishness, low muscle tone), and/or withdrawal symptoms (jitteriness, irritability, restlessness, shaking, excessive crying, feeding problems).
 - Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with RESTORIL.
 - There is a pregnancy registry for women who take RESTORIL during pregnancy. The purpose of the registry is to collect information about the health of women and their babies exposed to RESTORIL. If you become pregnant during treatment with RESTORIL, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychiatric Medications. You can register by calling 1-866-961-2388 or visiting <https://womensmentalhealth.org/research/pregnancyregistry/>.
- are breastfeeding, or plan to breastfeed. RESTORIL can pass through your breast milk.
 - Breastfeeding during treatment with RESTORIL may cause your baby to have sleepiness, feeding problems, and decreased weight gain.
 - 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 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?”**
- **Abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts.
- **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.
- **RESTORIL can make you sleepy or dizzy and can slow your thinking and motor skills.**
 - Do not drive, operate heavy machinery, or do other dangerous activities until you know how RESTORIL affects you.
 - **Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking RESTORIL without first talking to your healthcare provider.** When taken with alcohol or other drugs that cause sleepiness or dizziness, RESTORIL may make your sleepiness or dizziness much worse.

The most common side effects of RESTORIL include:

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|--------------|---------------|
| • 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 at room temperature 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.

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

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