

**Storage:** Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

**M** and Restoril are trademarks of Mallinckrodt Inc.

\*Romazicon is the registered trademark of Hoffman-LaRoche Inc.

\*\*Trademark of Medical Economics Company, Inc.

Mallinckrodt Inc.  
Hazelwood, MO 63042 U.S.A.

Rev 11/2010

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

Read the Medication Guide that comes with RESTORIL before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment.

---

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

**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 doctor right away if you find out that you have done any of the above activities after taking RESTORIL.**

**Important:**

**1. Take RESTORIL exactly as prescribed**

- Do not take more RESTORIL than prescribed.
- Take RESTORIL right before you get in bed, not sooner.

**2. Do not take RESTORIL if you:**

- drink alcohol
  - take other medicines that can make you sleepy. Talk to your doctor about all of your medicines. Your doctor will tell you if you can take RESTORIL with your other medicines.
  - cannot get a full night's sleep.
- 

### **What is RESTORIL?**

RESTORIL is a sedative-hypnotic (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
- waking up often during the night

RESTORIL is not for children.

RESTORIL is a federally 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 doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

### **Who should not take RESTORIL?**

**Do not take RESTORIL if you are pregnant or planning to become pregnant.** RESTORIL may cause birth defects or harm a fetus (unborn baby).

**RESTORIL may not be right for you. Before starting RESTORIL, tell your doctor about all of your health 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 kidney or liver disease
- have a lung disease or breathing problems
- are breastfeeding

Tell your doctor about all of the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Medicines can interact with each other, sometimes causing serious side effects. **Do not take RESTORIL with other medicines that can make you sleepy.**

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

### **How should I take RESTORIL?**

- Take RESTORIL exactly as prescribed. Do not take more RESTORIL than prescribed for you.
- **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.**
- **Call your doctor if your insomnia worsens or is not better within 7 to 10 days.** This may mean that there is another condition causing your sleep problems.
- If you take too much RESTORIL or overdose, call your doctor or poison control center right away, or get emergency treatment.

### What are the possible side effects of RESTORIL?

#### Possible serious side effects of RESTORIL include:

- **getting out of bed while not being fully awake and do an activity that you do not know you are doing.** (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.
- **memory loss**
- **anxiety**
- **severe allergic reactions.** Symptoms include swelling of the tongue or throat, trouble breathing, and nausea and vomiting. Get emergency medical help if you get these symptoms after taking RESTORIL.

**Call your doctor right away if you have any of the above side effects or any other side effects that worry you while using RESTORIL.**

#### The most common side effects of RESTORIL are:

- drowsiness
- headache
- tiredness
- nervousness
- dizziness
- nausea
- “hangover” feeling the day after taking RESTORIL
- 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.**
- You may have withdrawal symptoms if you stop taking RESTORIL suddenly. Withdrawal symptoms can be serious and include seizures. Mild withdrawal symptoms include a depressed mood and trouble sleeping. Talk to your doctor to check if you need to stop RESTORIL slowly.

These are not all the side effects of RESTORIL. Ask your doctor or pharmacist for more information.

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

### **General Information about 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 share RESTORIL with other people, even if you think they have the same symptoms that you have. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about RESTORIL. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about RESTORIL that is written for healthcare professionals, or you may also contact Mallinckrodt (the maker of RESTORIL) by visiting [www.Mallinckrodt.com](http://www.Mallinckrodt.com) or calling 1-800-778-7898.

### **What are the ingredients in RESTORIL?**

#### ***7.5 mg, 15 mg, 22.5 mg, and 30 mg Capsules***

*Active Ingredient:* temazepam USP

#### ***7.5 mg Capsules***

*Inactive Ingredients:* FD&C Blue #1, FD&C Red #3, gelatin, lactose, magnesium stearate, red iron oxide, titanium dioxide.

*May also include:* n-butyl alcohol, iron oxide red, shellac, shellac glaze, SD-35A alcohol.

#### ***15 mg Capsules***

*Inactive Ingredients:* FD&C Blue #1, FD&C Red #3, gelatin, lactose, magnesium stearate, red iron oxide, titanium dioxide.

*May also include:* n-butyl alcohol, FD&C Blue #1/Brilliant Blue FCF Aluminum Lake, iron oxide red, isopropyl alcohol, propylene glycol, shellac, shellac glaze, SD-35A alcohol, SD-45 alcohol.

#### ***22.5 mg Capsules***

*Inactive Ingredients:* FD&C Blue #1, FD&C Red #3, gelatin, lactose, magnesium stearate, red iron oxide, titanium dioxide.

*May also include:* n-butyl alcohol, FD&C Blue #1/Brilliant Blue FCF Aluminum Lake, iron oxide red, isopropyl alcohol, propylene glycol, shellac, shellac glaze, SD-35A alcohol, SD-45 alcohol.

**30 mg Capsules**

*Inactive Ingredients:* FD&C Blue #1, FD&C Red #3, gelatin, lactose, magnesium stearate, red iron oxide, titanium dioxide.

*May also include:* n-butyl alcohol, FD&C Blue #1/Brilliant Blue FCF Aluminum Lake, iron oxide red, isopropyl alcohol, propylene glycol, shellac, shellac glaze, SD-35A alcohol, SD-45 alcohol.

**Rx only**

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

RESTORIL is a trademark of Mallinckrodt Inc.

Mallinckrodt Inc.  
Hazelwood, MO 63042 U.S.A.

Printed in U.S.A.



**Mallinckrodt**

Rev 11/2010