

## MEDICATION GUIDE

### Intermezzo<sup>®</sup> (in ter mét zoh)

(zolpidem tartrate) sublingual tablet C-IV

Read the Medication Guide that comes with Intermezzo<sup>®</sup> 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 Intermezzo?**

**Follow the Instructions for Use at the end of this Medication Guide when you take Intermezzo. If you do not follow the Instructions for Use, you might be drowsy in the morning without knowing it.**

- **Only take one tablet a night, if needed.**
- **Only take Intermezzo if you have at least 4 hours of bedtime left.**

#### **Intermezzo may cause serious side effects, including:**

- **After taking Intermezzo, 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 drank alcohol that day or take other medicines that make you sleepy with Intermezzo. 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 Intermezzo.**

#### **Important:**

1. **Take Intermezzo exactly as prescribed**
2. **Do not take Intermezzo if you:**
  - drank alcohol that day or before bed.
  - took another medicine to help you sleep.
  - do not have at least 4 hours of bedtime remaining.

#### **What is Intermezzo?**

Intermezzo is a sedative-hypnotic (sleep) medicine. Intermezzo is used in adults for the treatment of a sleep problem called insomnia. Many people have difficulty returning to sleep after awakening in the middle of the night. Intermezzo is designed to specifically treat this problem.

It is not known if Intermezzo is safe and effective in children.

Intermezzo is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep Intermezzo in a safe place to prevent misuse and abuse. Selling or giving away Intermezzo may harm others, and is against the law. Tell your doctor if you have ever abused or have been dependent on alcohol, prescription medicines, or street drugs.

### **Who should not take Intermezzo?**

- Do not take Intermezzo if you are allergic to zolpidem or any other ingredients in Intermezzo. See the end of this Medication Guide for a complete list of ingredients in Intermezzo.
- Do not take Intermezzo if you have had an allergic reaction to drugs containing zolpidem, such as Ambien, Ambien CR, Edluar, or Zolpimist.

### **Symptoms of a serious allergic reaction to Intermezzo can include:**

- **swelling of your face, lips, and throat that may cause difficulty breathing or swallowing**
- **nausea and vomiting**

### **Intermezzo may not be right for you. Before starting Intermezzo, 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 pregnant, planning to become pregnant, or 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. Your doctor will tell you if you can take Intermezzo with your other medicines.

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 Intermezzo?**

- See **“What is the most important information I should know about Intermezzo”**
- Read the **“Instructions for Use”** at the end of this Medication Guide for detailed instructions on how to take Intermezzo.
- Take Intermezzo exactly as prescribed. Only take one Intermezzo tablet per night if needed.
- Do not take Intermezzo if you drank alcohol that evening or before bed.
- While in bed, place the tablet under your tongue and allow it to break apart completely. Do not swallow it whole.
- You should not take Intermezzo with or right after a meal. Intermezzo may help you fall asleep faster when you take it on an empty stomach.
- Call your health care provider if your insomnia worsens or is not better within 7 to 10 days. This may mean that there is another condition causing your sleep problem.
- If you take too much Intermezzo or overdose get emergency treatment.

#### **What are the possible side effects of Intermezzo?**

Intermezzo may cause serious side effects, including:

- **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 Intermezzo?”)
- **abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts or actions.
- **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 Intermezzo.

**Call your health care provider right away if you have any of the above side effects or any other side effects that worry you while using Intermezzo.**

**The most common side effects of Intermezzo are:**

- Headache
- Nausea
- Fatigue

Even if you follow the Instructions for Use, you may still feel drowsy in the morning after taking Intermezzo. Do not drive or do other dangerous activities after taking Intermezzo until you are fully awake.

These are not all the side effects of Intermezzo. Ask your health care provider or pharmacist for more information.

You may report side effects to FDA at 1-800-FDA-1088.

### **How should I store Intermezzo?**

- Store Intermezzo at room temperature, 68° to 77°F (20° to 25°C). Protect from moisture.
- Only open the pouch when you are ready to use Intermezzo.

**Keep Intermezzo and all medicines out of reach of children.**

### **General Information about Intermezzo**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Intermezzo for a condition for which it was not prescribed. Do not give Intermezzo to 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 Intermezzo. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Intermezzo that is written for healthcare professionals. For more information about Intermezzo, call 1-888-619-0188 or visit [www.intermezzo-usa.com](http://www.intermezzo-usa.com).

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

**Active Ingredient:** Zolpidem tartrate

**Inactive Ingredients:** Each Intermezzo tablet includes the following inactive ingredients: mannitol, sorbitol, crospovidone, silicon dioxide, sodium carbonate, sodium bicarbonate, croscarmellose sodium, sodium stearyl fumarate, silicon dioxide, natural and artificial spearmint flavor, silicon dioxide-colloidal, and sucralose. The 1.75 mg tablet also contains yellow iron oxide, and the 3.5 mg tablet contains beige iron oxide.

### **R<sub>x</sub> only**

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

Manufactured for Transcept Pharmaceuticals, Inc.  
Point Richmond, CA 94804.

November , 2011

**Instructions for Use**  
**Intermezzo® (in ter mét zoh)**  
**(zolpidem tartrate) sublingual tablet C-IV**

Read these Instructions for Use before you start taking Intermezzo and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

**What is the most important Information I should know about Intermezzo?**

Follow these Instructions for Use when you take Intermezzo. If you do not follow these instructions, you might be drowsy in the morning without knowing it.

- Only take 1 tablet a night if needed
- Only take Intermezzo if you have at least 4 hours of bedtime left

**Using Intermezzo the wrong way can make you drowsy in the morning.**

**Before you go to bed:**

- Place only 1 Intermezzo pouch by your bed, and have a clock or watch nearby (see Figure A).



**Figure A**

- Store all other unopened Intermezzo pouches with your other medicines away from your bedside.
- Only open the Intermezzo pouch when you are ready to use it.
- You can either use the **Intermezzo Dosing Time Chart** (see Figure B) or the **Dosing Time Tool** (see Figure C) that comes with Intermezzo to find the latest time during the night you can take Intermezzo.

**Intermezzo Dosing Time Chart (see Figure B):**

- You can take Intermezzo if you have at least 4 hours of bedtime left before you must be awake.

- Find the earliest time you have to be up and awake in the column on the left.
- Find the latest time you can take Intermezzo on the same line in the column on the right.

**Intermezzo Dosing Time Chart**

| <b>If you must be awake by:</b> | <b>Take Intermezzo before:</b> |
|---------------------------------|--------------------------------|
| 4 am                            | 12 midnight                    |
| 5 am                            | 1 am                           |
| 6 am                            | 2 am                           |
| 7 am                            | 3 am                           |
| 8 am                            | 4 am                           |
| 9 am                            | 5 am                           |

**Figure B**

**Intermezzo Dosing Time Tool (see Figure C):**

- Turn the Intermezzo Dosing Time Tool wheel to show the earliest time that you must be awake under the green arrow.

Take Intermezzo before the time under the brown arrow.



**Figure C**

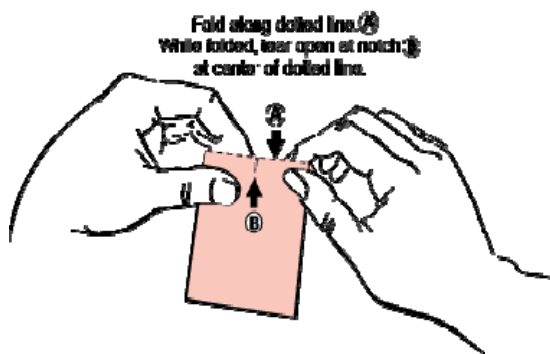
**During the night when you take Intermezzo:**

**Step 1.** Check the current time and use the Intermezzo Dosing Time Chart or the Intermezzo Dosing Time Tool to decide if you should take Intermezzo.

- Only take Intermezzo if you have at least 4 hours of bedtime left before you have to be awake (see Figure B).

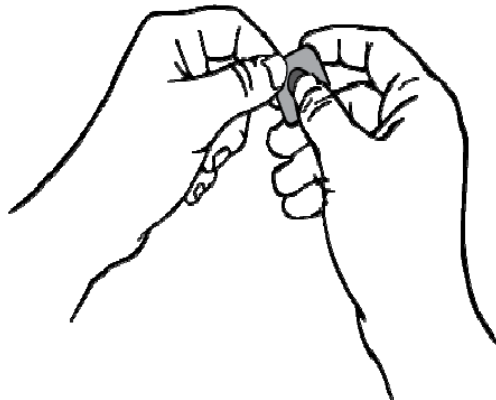
**Step 2.** Open the Intermezzo pouch you placed by your bed.

- Fold the Intermezzo pouch along the dotted line. While the Intermezzo pouch is folded, tear the pouch open at the notch at the center of the dotted line (see Figure D).



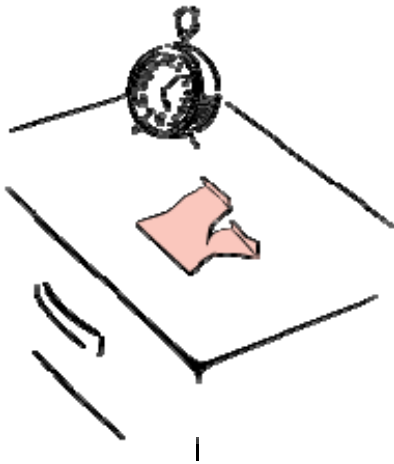
**Figure D**

**Step 3.** Remove the foil blister from the Intermezzo pouch. Push the Intermezzo tablet through the foil (see Figure E).



**Figure E**

**Step 4.** Leave the empty Intermezzo pouch where you can see it. The empty pouch will help remind you that you already took your Intermezzo dose (see Figure F).



**Figure F**

**Step 5.** While in bed, place the Intermezzo tablet under your tongue and allow it to break apart completely, then swallow. Do not swallow it whole. (see Figure G)



**Figure G**

**Step 6.** Throw the empty Intermezzo pouch away in the morning.

**When you wake up in the morning,** be sure that at least 4 hours have passed since you have taken Intermezzo and you feel fully awake before driving. Do not do dangerous activities until you know how Intermezzo affects you.

This Medication Guide and Instructions for Use have been approved by the U.S. Food and Drug Administration.

Manufactured by:

Transcept Pharmaceuticals, Inc.

Pt. Richmond, CA 94084

11/2011