A Pharmacist’s Guide to Intermezzo

Intermezzo® (zolpidem tartrate) is indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep.

Limitations of Use: Intermezzo is not indicated for the treatment of middle-of-the-night insomnia when the patient has fewer than 4 hours of bedtime remaining before the planned time of waking.

Important Safety Information

• Intermezzo is contraindicated in patients with known hypersensitivity to zolpidem. Observed reactions with zolpidem include anaphylaxis and angioedema.
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Why dispense Intermezzo as prescribed?

3 Key points a pharmacist should know

1. There is no AB rated generic equivalent for the two available doses of Intermezzo—1.75 mg and 3.5 mg.
2. Intermezzo is the first and only prescription sleep aid approved for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep with at least 4 hours left for sleep.
3. Intermezzo has been studied in patients with middle-of-the-night insomnia.

There is no AB rated equivalent for the two available doses of Intermezzo (1.75 mg and 3.5 mg). No other prescription sleep aid should be substituted for Intermezzo.

Important Safety Information

- Co-administration with Intermezzo and other CNS depressants increases the risk of CNS depression. Intermezzo should not be taken with alcohol. The use of Intermezzo with other sedative-hypnotics (including other zolpidem products) at bedtime or the middle of the night is not recommended.
- The risk of next-day driving impairment (and psychomotor impairment) is increased if Intermezzo is taken with less than 4 hours of bedtime remaining; if a higher than recommended dose is taken; if co-administered with other CNS depressants; or co-administered with other drugs that increase the blood levels of zolpidem. A small negative effect on SDLP (standard deviation of lateral position, a measure of driving impairment) may remain in some patients 4 hours after taking Intermezzo, such that a potential negative effect on driving cannot be completely excluded.

Please read accompanying Full Prescribing Information.
Intermezzo is the first and only prescription sleep aid approved for once-nightly, as-needed dosing for middle-of-the-night awakenings if your patient has at least 4 hours of sleep left.

Discuss the following important administration instructions with your patients when providing them with Intermezzo® (zolpidem tartrate). Remind them to read the Instructions for Use section in the Medication Guide for detailed instructions on how to take Intermezzo.

**Dosage and administration**

**Important administration instructions**
- **Intermezzo** is to be taken in bed when a patient wakes in the middle of the night and has difficulty returning to sleep.
- **Intermezzo** should only be taken if the patient has at least 4 hours of bedtime remaining before the planned time of waking.
- **Intermezzo** should be placed under the tongue and allowed to disintegrate completely before swallowing.
- The tablet should not be swallowed whole.
- For optimal effect, **Intermezzo** should not be administered with or immediately after a meal.
- The blister should be removed from the pouch just prior to dosing.
- **Intermezzo** should not be taken if alcohol was consumed that day or before bed.

**Recommended dosing**
- The recommended and maximum dose of Intermezzo is 1.75 mg for women and 3.5 mg for men, taken only once per night as needed if a middle-of-the-night awakening is followed by difficulty returning to sleep. The recommended doses for women and men are different because women clear zolpidem from the body at a lower rate than men.
- The recommended Intermezzo dose for men and women who are taking concomitant CNS depressants is 1.75 mg.
- Dose adjustment of concomitant CNS depressants may be necessary when co-administered with Intermezzo because of potentially additive effects.
- The use of Intermezzo with other sedative-hypnotics (including other zolpidem products) at bedtime or the middle of the night is not recommended.
- Geriatric patients may be especially sensitive to the effects of zolpidem.
- The recommended dose of Intermezzo in men and women over 65 years old and patients with hepatic impairment is 1.75 mg, taken only once per night if needed.
Important information to review with patients

Inform patients and their families about the benefits and risks of treatment with Intermezzo. Inform patients of the availability of a Medication Guide and instruct them to read the Medication Guide prior to initiating treatment with Intermezzo and with each prescription refill. Review the Intermezzo Medication Guide with every patient prior to initiation of treatment. Instruct patients or caregivers that Intermezzo should be taken only as prescribed.

CNS depressant effects and next-day impairment

- Tell patients that Intermezzo has the potential to cause next-day impairment, and that this risk is increased if dosing instructions are not carefully followed
- Tell patients to wait for at least 4 hours after dosing and until they feel fully awake before driving or engaging in other activities requiring full mental alertness

Severe anaphylactic and anaphylactoid reactions

- Inform patients that severe anaphylactic and anaphylactoid reactions have occurred with zolpidem
- Describe the signs/symptoms of these reactions and advise patients to seek medical attention immediately if any of them occur

Sleep-driving and other complex behaviors

- Instruct patients to inform their families that zolpidem has been associated with “sleep-driving” and other complex behaviors while not being fully awake (preparing and eating food, making phone calls, or having sex)
- Tell patients and their families to call their healthcare providers immediately if they develop any of these symptoms

Suicide

- Tell patients to immediately report any suicidal thoughts to their healthcare provider

Important Safety Information

- The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated.
- Cases of angioedema involving the tongue, glottis, or larynx have been reported in patients after taking the first or subsequent doses of zolpidem. Some patients have had additional symptoms such as dyspnea, throat closing, or nausea and vomiting that suggest anaphylaxis. Some patients have required medical therapy in the emergency department. Angioedema, and additional symptoms suggesting anaphylaxis, may occur in patients taking zolpidem and may be fatal. Patients who develop angioedema or anaphylaxis should not be rechallenged.
Help patients save with Intermezzo

Patients can get a free 3-day trial with a valid 3-tablet prescription for Intermezzo AND they may be eligible to save up to $45 on their prescriptions for Intermezzo with the Savings Card.

Free 3-day trial of Intermezzo

• The Intermezzo Trial Offer allows all patients with a valid 3-tablet prescription for Intermezzo to receive a 3-day trial of Intermezzo at no cost
• There is a limit of one Trial Offer per patient and the card expires 3/31/2013
• Patients must meet the Terms and Conditions

Intermezzo Savings Card

• The patient is responsible for the first $15 and any amount that exceeds the total Intermezzo Patient Savings Card offer
• Only valid for prescriptions written for a minimum of 20 tablets
• Medicare/Medicaid patients and patients insured by federal or state government programs are not eligible to use this Savings Card
• A valid prescription must accompany each Intermezzo Savings Card at time of first use
• Patients can use their Intermezzo Savings Card every 28 days until the offer expires on 3/31/2013
• Patients must meet the Eligibility Requirements and Terms and Conditions

To learn more about the Intermezzo Savings Card and Free Trial Offer, scan this code with your smartphone or visit IntermezzoRX.com

Intermezzo®
(ZOLPIDEM TARTRATE) sublingual tablet®
1.75 mg | 3.5 mg
Important Safety Information

- Abnormal thinking and behavior changes have been reported in patients treated with a sedative-hypnotic including zolpidem. Complex behaviors, including driving or eating while not fully awake, with amnesia for the event, as well as visual and auditory hallucinations and abnormal behaviors such as decreased inhibition, bizarre behavior, agitation, and depersonalization may occur. Although behaviors such as “sleep-driving” have occurred with zolpidem alone at therapeutic doses, the co-administration of zolpidem with alcohol and other CNS depressants increases the risk of such behaviors, as does the use of zolpidem at doses exceeding the maximum recommended dose. Discontinuation of Intermezzo should be strongly considered for patients reporting a “sleep-driving” episode.

- In primarily depressed patients, worsening of depression, including suicidal thoughts and actions (including completed suicides) have been reported with the use of sedative-hypnotics. Intentional overdosage is more common in this group of patients; therefore, protective measures may be required and prescribe the least amount of Intermezzo that is feasible.

- Because persons with a history of addiction to or abuse of drugs or alcohol are at increased risk for misuse, abuse, and addiction of zolpidem, they should be monitored carefully when receiving Intermezzo. Zolpidem tartrate is a Schedule IV controlled substance. Post-marketing reports of abuse, dependence, and withdrawal resulting from use of oral zolpidem tartrate have been received. Zolpidem has produced withdrawal signs and symptoms following a rapid dose decrease or abrupt discontinuation.

- The most commonly observed adverse reactions (>1%) were headache (Intermezzo 3%, placebo 1%), nausea (1% for both patient groups), and fatigue (Intermezzo 1%, placebo 0%).

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