Summary of prescribing information for ZEDTIME tablets

Active Ingredient: Each film coated tablet of ZEDTIME contains: zolpidem tartrate-5mg,10mg. **Indication:** Short term treatment of insominia. **Dosage:** Use the lowest dose effective for the patient and must not exceed a total of 10 mg daily. Recommended initial dose is a single dose of 5 mg for women and a single dose of 5 or 10 mg for men, immediately before bedtime with at least 7-8 hours remaining before the planned time of awakening. Geriatric patients and patients with mild to moderate hepatic impairment: Recommended dose is 5 mg for men and women. The effect of may be slowed if taken with or immediately after a meal. **Contraindications:** Patients who have experienced complex sleep behaviors after taking zolpidem, Known hypersensitivity to zolpidem or any ingredient. **Warning and precautions:** CNS-Depressant Effects: Impairs alertness and motor coordination including risk of morning impairment. Risk increases with dose and use with other CNS depressants and alcohol. Instruct patients on correct use. Need to Evaluate for Comorbid Diagnoses: Re-evaluate if insomnia persists after 7 to 10 days of use. Severe Anaphylactic/Anaphylactoid Reactions: Angioedema and anaphylaxis have been reported. Do not rechallenge if such reactions occur. Abnormal Thinking and Behavioral Changes: Changes including decreased inhibition, bizarre behavior, agitation, and depersonalization have been reported. Immediately evaluate any new onset behavioral changes. Depression: Worsening of depression or suicidal thinking may occur. Prescribe the least amount of tablets feasible to avoid intentional overdose. Respiratory Depression: Consider this risk before prescribing in patients with compromised respiratory function. Hepatic Impairment: Avoid zolpidem use in patients with severe hepatic impairment. Withdrawal Effects: Symptoms may occur with rapid dose reduction or discontinuation. **Pregnancy & Lactation:** Pregnancy: May cause respiratory depression and sedation in neonates with exposure late in the third trimester. Lactation: A lactating woman may pump and discard breast milk during treatment and for 23 hours after zolpidem administration. **Interaction:** CNS depressants, including alcohol: Possible adverse additive CNS depressant effects. Imipramine: Decreased alertness observed. Chlorpromazine: Impaired alertness and psychomotor performance observed. CYP3A4 inducers (rifampin or St. John's wort): Combination use may decrease effect. Ketoconazole: Combination use may increase effect. **Adverse reactions:** Most commonly: Short-term (<10 nights): Drowsiness, dizziness, and diarrhea; Long-term (28-35 nights): Dizziness and drugged feelings. **Overdose:** Symptoms: impairment of consciousness ranging from somnolence to coma, cardiovascular and/or respiratory compromise, and fatal outcomes have been reported. Management: General symptomatic and supportive measures should be used along with immediate gastric lavage where appropriate. Intravenous fluids should be administered as needed. Flumazenil may be useful. However, flumazenil administration may contribute to the appearance of neurological symptoms (convulsions). Respiration, pulse, blood pressure, and other appropriate signs should be monitored. Hypotension and CNS depression should be monitored and treated by appropriate medical intervention. Sedating drugs should be withheld, even if excitation occurs. The value of dialysis in the treatment of overdosage has not been determined.

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It is recommended to refer full prescribing information before prescription.

For further medical information, please write to: Intas Pharmaceuticals Ltd., Corporate House, Near Sola Bridge, SG highway, Thaltej, Ahmedabad-380054, Gujarat, India. productqueries@intaspharma.com