For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

STILNOCT®

Zolpidem Tartrate prolonged release tablets IP

COMPOSITION: Each film coated bilayered tablet contains zolpidem tartrate I.P. 12.5mg or 6.25mg.

THERAPEUTIC INDICATIONS: For the short-term treatment of insomnia in adults, characterised by difficulties with sleep onset and/or sleep maintenance.

DOSAGE AND ADMINISTRATION: STILNOCT® acts rapidly and therefore should be taken immediately before retiring or in bed. STILNOCT® should be taken in a single intake and not be re-administered during the same night. Long term use of Zolpidem is not recommended. Treatment should be as short as possible and should not exceed four weeks. Extension beyond the maximum treatment period should not take place without re-evaluation of the patient's status, since the risk of abuse and dependence increases with the duration of treatment.

Pediatric patients: Safety and effectiveness of zolpidem in pediatric patients under the age of 18 years have not been established. Therefore, zolpidem should not be prescribed in this population.

Elderly: Since elderly or debilitated patients may be especially sensitive to the effects of zolpidem, in these subjects a 6.25 mg dose is recommended.

Hepatic impairment: As clearance and metabolism of zolpidem is reduced in hepatic impairment, dosage should begin at 6.25 mg in these patients with hepatic impairment with particular caution being exercised in elderly patients.

SAFETY-RELATED INFORMATION

Contraindications: Zolpidem is contraindicated in patients with: Hypersensitivity to zolpidem or any of the inactive ingredients; severe hepatic insufficiency; acute and/or severe respiratory insufficiency and who have previously experienced complex sleep behaviors after taking STILNOCT®

Warnings/Precautions: Use with caution in patients with sleep apnea syndrome, and myasthenia gravis. Respiratory insufficiency: as hypnotics have the capacity to depress respiratory drive, precautions should be observed. Risks from concomitant use with opioids: Concomitant use of opioids with benzodiazepines or other sedative-hypnotic drugs, including zolpidem, may result in sedation, respiratory depression, coma, and death. Because of these risks, reserve concomitant prescribing of opioids and benzodiazepines for use in patients for whom alternative treatment options are inadequate. If a decision is made to prescribe zolpidem concomitantly with opioids, prescribe the lowest effective dosages and minimum durations of concomitant use, and follow patients closely for signs and symptoms of respiratory depression and sedation. Hepatic Insufficiency: Zolpidem must not be used in patients with severe hepatic impairment as it may contribute to encephalopathy. The failure of insomnia to remit after a 7–14-day course of treatment may indicate the presence of a primary psychiatric or physical disorder, and the patient should be carefully re-evaluated at regular intervals. Paediatric patients: Safety and effectiveness of zolpidem have not been established in patients below the age of 18 years. Elderly patients: see dose recommendations. Psychotic illness: Hypnotics such as zolpidem are not recommended for the primary treatment of psychotic illness. Amnesia: Sedative/hypnotic agents such as zolpidem may induce anterograde amnesia. The condition occurs most often several hours after ingesting the product and therefore to reduce the risk patients should ensure that they will be able to have an uninterrupted sleep of 7-8 hours. Suicidality and depression: Several epidemiological studies show an increased incidence of suicide and suicide attempt in patients with or without depression, treated with benzodiazepines and other hypnotics, including zolpidem. A causal relationship has not been established. Zolpidem should be administered with caution in patients exhibiting symptoms of depression. Suicidal tendencies may be present, therefore the least amount of zolpidem that is feasible should be supplied to these patients to avoid the possibility of intentional overdosage by the patient. Other psychiatric and "paradoxical" reactions: Other psychiatric and paradoxical reactions like restlessness, insomnia exacerbated, agitation, irritability, aggression, delusion, anger, nightmares, hallucinations, abnormal behavior, delirium and other adverse behavioral effects are known to occur when using sedative/hypnotic agents like zolpidem. These reactions are more likely to occur in the elderly. Somnambulism and associated behaviors: Complex sleep behaviors, including sleepwalking, sleep-driving, and engaging in other activities while not fully awake, may occur following the first or any subsequent use of STILNOCT®. Patients can be seriously injured or injure others during complex sleep behaviors. Such injuries may be fatal. Other complex sleep behaviors (e.g., preparing and eating food, making phone calls, or having sex) have also been reported. Patients usually do not remember these events. Post marketing reports have shown that complex sleep behaviors may occur with STILNOCT® alone at recommended doses, with or without the concomitant use of alcohol or other central nervous system (CNS) depressants. Discontinue STILNOCT® immediately if a patient experiences a complex sleep behavior. Psychomotor impairment: like other sedative / hypnotic drugs zolpidem has CNS-depressant effects. Tolerance: Some loss of efficacy with respect to the hypnotic effects of sedative/hypnotic agents like zolpidem may develop after repeated use for a few weeks. Dependence: Use of zolpidem may lead to the development of abuse and/or physical and psychological dependence. The risk of dependence increases with dose and duration of treatment. Cases of dependence have been reported more frequently in patients treated with STILNOCT® for longer than 4 weeks. The risk of abuse and dependence is also greater in patients with a history of psychiatric disorders and/or alcohol or drug abuse. STILNOCT® should be used with extreme caution in patients with current or a history of alcohol or drug abuse. Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms. Rebound insomnia: A transient syndrome whereby the symptoms that led to treatment with sedative/hypnotic agents recur in an enhanced form, may occur on withdrawal of hypnotic treatment. Severe injuries: Due to its pharmacological properties, zolpidem can cause drowsiness and a decreased level of consciousness, which may lead to falls and consequently to severe injuries. Patients with long QT syndrome: As a precaution, the benefit/risk ratio of zolpidem treatment in patients with known congenital long QT syndrome should be carefully considered. Chemical submission (Drug facilitated illicit use for criminal intent)**:** The rapid onset of sedation, coupled with the amnestic features of STILNOCT®, particularly when combined with alcohol, administered without knowledge of the victim, has proven to induce incapacitation and thus

facilitate criminal actions (which could be dangerous). Healthcare Providers should prescribe according to their clinical evaluation and only in case of medical need as it may be used illicitly for chemical submission.

PREGNANCY & LACTATION: The use of zolpidem is not recommended during pregnancy. Use of zolpidem in nursing mothers is not recommended.

DRIVING A VEHICLE OR PERFORMING OTHER HAZARDOUS TASKS: Vehicle drivers and machine operators should be warned of a possible risk of adverse reactions including drowsiness prolonged reaction time, dizziness, sleepiness, blurred/ double vision, reduced alertness and impaired driving the morning after therapy. To minimize this risk a full of night sleep (7-8h) is recommended. Furthermore, the co-administration of zolpidem with alcohol and other CNS depressants increases the risk of such effects. Patients should be warned not to use alcohol or other psychoactive substances when taking zolpidem.

ADVERSE REACTIONS: *Very common*: Headache, somnolence. *Common:* Influenza, anxiety, psychomotor retardation, disorientation, dizziness, cognitive disorders such as memory disorders (memory impairment, amnesia, anterograde amnesia) disturbance in attention, visual disturbance, nausea, constipation, myalgia, muscle cramp, neck pain, back pain, fatigue.

For full prescribing information, please contact: Sanofi Healthcare India Private Limited, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072.

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