



Eszopiclone INN Tablet.

Presentation:

Sleepon[®] 1 tablet: Each film-coated tablet contains Eszopiclone INN 1 mg.

Sleepon[®] 2 tablet: Each film-coated tablet contains Eszopiclone INN 2 mg.

Description:

Sleepon[®], the preparation of Eszopiclone (s-isomer of Zopiclone) is a sedative/hypnotic. It is a non-benzodiazepine that works via interaction with GABA-receptor complexes. It is rapidly absorbed and have elimination half-life (t_{1/2}) of approx. 6 hours in non-elderly adults. In the elderly, half life is approx. 9 hours.

Indications:

Sleepon[®] is indicated for the management of insomnia, including difficulty in falling asleep, difficulty in maintaining sleep during the night, and waking up too early in the morning.

Dosage and administration:

The dose of **Sleepon**[®] should be individualized. The recommended oral starting dose for most non-elderly adults (ages 18 to 64) is 2 mg immediately before bedtime. Dosing can be initiated at or increased to 3 mg as clinically indicated.

The recommended oral starting dose for elderly patients (ages 65 and older) who have difficulty falling asleep is 1 mg immediately before bedtime. In these patients, the dose may be increased to 2 mg as clinically indicated. For elderly patients who have difficulty staying asleep, the recommended dose is 2 mg immediately before bedtime.

Pediatric dosing is not available.

Taking **Sleepon**[®] with or immediately after a heavy, high-fat meal results in slower absorption and would be expected to reduce the effect of **Sleepon**[®] on sleep latency.

Side effects:

The most common side effects of sleep medicines are Drowsiness, dizziness, lightheadedness, hallucination, difficulty with coordination.

Use in pregnancy and lactation:

Eszopiclone is pregnancy category C. There are no adequate and well-controlled studies of **Sleepon**[®] (Eszopiclone) in pregnant women. **Sleepon**[®] should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether Eszopiclone is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **Sleepon**[®] is administered to a nursing woman.

Precautions:

Sleepon[®] should be administered with caution in patients exhibiting signs and symptoms of depression. Therefore, the smallest dose feasible should be prescribed to the patient. Caution should be exercised in administration of **Sleepon**[®] to patients with compromised respiratory function. Use of benzodiazepines and similar agents may lead to physical and psychological dependence. Tolerance may develop after repeated use of benzodiazepines and benzodiazepine-like agents for a few weeks. However, no evidence of developed tolerance was seen with Eszopiclone over a period of 6 months in clinical trials.

Safety information:

Sleepon[®] should only be taken immediately before bedtime. Patients should not engage in any activity after taking **Sleepon**[®] that requires complete alertness, such as driving car or operating machinery etc. Patient should not use alcohol while taking **Sleepon**[®].

Drug interactions:

Eszopiclone is metabolized by the CYP450 liver enzymes; substrate for 3A4 & 2E1. It is recommended that the dose of eszopiclone be reduced in patients who are administered potent inhibitors of CYP3A4 (e.g. Itraconazole, Clarithromycin, Erythromycin, Nefazodone, Troleandomycin, Ritonavir, Nelfinavir). An additive impairment of psychomotor performance was seen with co-administration of Eszopiclone and Ethanol. An increased bioavailability was seen when Eszopiclone was co-administered with Ketoconazole. No clinically significant drug-drug interactions have been seen with Warfarin, Digoxin, Lorazepam, Paroxetine.

Overdosage:

There is limited pre-marketing clinical experience with the effects of an over dosage of Eszopiclone. In clinical trials with Eszopiclone, one case of overdose with up to 36 mg of Eszopiclone was reported in which the subject is fully recovered.

Commercial Pack:

Sleepon[®] 1 tablet: Each box contains 50's tablets in blister pack.

Sleepon[®] 2 tablet: Each box contains 50's tablets in blister pack.

Manufactured by:
 **Silva**
Pharmaceuticals Limited
Majdee, Noakhali, Bangladesh