Suvotol™

Suvorexant 10 mg

Composition
Suvotol™ 10 tablet: Each tablet contains Suvorexant INN 10 mg.

Pharmacology
Suvorexant is a highly selective antagonist for orexin receptors OX1R and OX2R. The mechanism by which Suvorexant exerts its therapeutic effect in insomnia is presumed to be through antagonism of orexin receptors. The orexin neuropeptide signaling system is a central promoter of wakefulness. Blocking the binding of wake-promoting neuropeptides orexin A and orexin B to receptors OX1R and OX2R is thought to suppress wake drive.

Indication & Usage
Suvotol™ is indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Dosage & Administration
Recommended dose is 10 mg, no more than once per night taken before 30 minutes of going to bed, with at least 7 hours remaining before the planned time of awakening. If the 10 mg dose is well-tolerated but not effective, the dose can be increased, not to exceed 20 mg once daily. Lowest dose effective should be used for the patient.
Time to effect may be delayed if taken with or soon after a meal.

Side Effects
- Sleepiness during the day
- Not thinking clearly
- Act strangely, confused, or upset
- Sleep-walking

Special Warning & Precautions
Daytime somnolence: Risk of impaired alertness and motor coordination, including impaired driving; risk increases with dose; caution patients taking 20 mg against next-day driving and other activities requiring complete mental alertness. Need to evaluate for co-morbid diagnoses: Reevaluate if insomnia persists after 7 to 10 days of treatment.

Contraindications
Do not use in patients with narcolepsy.

Drug Interaction
CNS-Active Drugs
An additive effect on psychomotor performance was observed when a single dose of 40 mg of Suvorexant was co-administered with a single dose of 0.7 g/kg alcohol. Suvorexant does not affect alcohol concentrations and alcohol does not affect Suvorexant concentrations.

Effects of Other Drugs on Suvorexant
Strong (e.g., ketoconazole or itraconazole) and moderate (e.g., diltiazem) CYP3A inhibitors significantly increased Suvorexant exposure. Strong CYP3A inducers (e.g., rifampin) substantially decreases Suvorexant exposure.

Effects of Suvorexant on Other Drugs
Suvorexant is unlikely to cause clinically significant inhibition of human CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19 or CYP2D6. Chronic administration of Suvorexant is unlikely to induce the metabolism of drugs metabolized by major CYP isoforms.

Use in Pregnancy & Lactation
Pregnancy Category C.
There is no adequate and well-controlled studies in pregnant women. Suvorexant should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Storage
Store in dry and cool place, protect from light & keep away from children.

How Supplied
Suvotol™ 10 tablet: Each box contains 10 tablets in blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
Pabna, Bangladesh

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