

Suvo[®]

Suvorexant INN Film Coated Tablet

DESCRIPTION

Suvo[®] is a preparation of Suvorexant. 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.

INDICATIONS

Indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

DOSAGE AND ADMINISTRATION

Use the lowest dose effective for the patient.

The recommended dose is 10 mg, taken no more than once per night and within 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. The maximum recommended dose of Suvorexant is 20 mg once daily.

CONTRAINDICATIONS

Suvorexant is contraindicated in patients with narcolepsy.

SIDE EFFECTS

- Dizziness
- Somnolence

PRECAUTION AND WARNING

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. Nighttime “sleep-driving” and other complex behaviors while out of bed and not fully awake. Risk increases with dose, with use of CNS depressants, and with alcohol. Depression: Worsening of depression or suicidal thinking may occur. Risk increases with dose. Immediately evaluate any new behavioral changes.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. There are 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. It is not known whether this drug is secreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Suvorexant is administered to a nursing woman.

PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Suvo[®] tablet: Box containing 1 strip of 10 tablets. Each film coated tablet contains Suvorexant INN 10 mg.

SK+F

Manufactured for

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

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