Fliban™

Flibanserin 100 mg

COMPOSITION : Each film coated tablet contains Flibanserin INN 100 mg.

PHARMACOLOGY : Flibanserin's mechanism of action is attributed to its high affinity for 5-HTA1 & 5-HTA2 receptors, displaying agonist activity on 5-HTA1 & antagonist on 5-HTA2, resulting in lowering of serotonin in the brain as well as an effect on increasing norepinephrine and dopamine neurotransmitters.

INDICATIONS : Flibanserin is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:

- A co-existing medical or psychiatric condition
- Problems within the relationship
- The effects of a medication or other drug substance

It is not indicated for the treatment of HSDD in postmenopausal women or in men.

DOSAGE AND ADMINISTRATION : The recommended dosage of Flibanserin is 100 mg administered orally once per day at bedtime. If a dose of Flibanserin is missed at bedtime, instruct the patient to take the next dose at bedtime on the next day. Instruct the patient to not double the next dose.

CONTRAINDICATIONS

Flibanserin is contraindicated:

- With use of alcohol: The use of Flibanserin and alcohol increases the risk of severe hypotension and syncope. Therefore, alcohol use is contraindicated in patients taking Flibanserin. With concomitant use with moderate or strong CYP3A4 inhibitors: The concomitant use of Flibanserin and moderate or strong CYP3A4 inhibitors increases Flibanserin concentrations, which can cause severe hypotension and syncope. Therefore, the use of moderate or strong CYP3A4 inhibitors is contraindicated in patients taking Flibanserin.
- In patients with hepatic impairment: The use of Flibanserin in patients with hepatic impairment increases Flibanserin concentrations, which can cause severe hypotension and syncope. The use of Flibanserin in patients with hepatic impairment increases Flibanserin concentrations, which can cause severe hypotension and syncope.

PRECAUTIONS

- Hypotension and Syncope with Flibanserin Alone: Patients with pre-syncope should immediately lie supine and promptly seek medical help if symptoms do not resolve.
- Central Nervous System (CNS) Depression (e.g., Somnolence, Sedation): Can occur with Flibanserin alone. Exacerbated by other CNS depressants, and in settings where Flibanserin concentrations are increased. Patients should avoid activities requiring full alertness (e.g., operating machinery or driving) until at least 6 hours after each dose and until they know how Flibanserin affects them.

USE IN PREGNANCY & LACTATION : There are no studies of Flibanserin in pregnant women to inform whether there is a drug-associated risk in humans. In animals, fetal toxicity only occurred in the presence of significant maternal toxicity including reductions in weight gain & sedation.

PEDIATRIC & GERIATRIC USE : Flibanserin is not indicated for use in pediatric patients. Flibanserin is not indicated for use in geriatric patients. Safety and effectiveness have not been established in geriatric patients.

DRUG INTERACTION

Oral Contraceptives and Other Weak CYP3A4 Inhibitors: Increases Flibanserin exposures and incidence of adverse reactions.
Strong CYP2C19 Inhibitors: Increases Flibanserin exposure which may increase risk of hypotension, syncope, and CNS depression.
CYP3A4 Inducers: Use of Flibanserin not recommended; Flibanserin concentrations substantially reduced.
Digoxin: Increases digoxin concentrations, which may lead to digoxin toxicity. Increase monitoring of digoxin concentrations.

ADVERSE EFFECTS

Most common adverse reactions (incidence ≥2%) are dizziness, somnolence, nausea, fatigue, insomnia, and dry mouth.

STORAGE : Store below 30°C. Protect from light & moisture. Keep all medicines out of the reach of children.

HOW SUPPLIED : Each box contains 10 tablets in alu-alu blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH