

VALZ

To be sold by retail on the prescription of 'Psychiatrist'

Abbreviated Prescribing information for VALZ (Vilazodone Hydrochloride Tablets)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: The mechanism of the antidepressant effect of vilazodone is not fully understood but is thought to be related to its enhancement of serotonergic activity in the CNS through selective inhibition of serotonin reuptake. Vilazodone is also a partial agonist at serotonergic 5-HT_{1A} receptors; however, the net result of this action on serotonergic transmission and its role in vilazodone's antidepressant effect are unknown.

INDICATION: Vilazodone is indicated for the treatment of major depressive disorders (MDD) in adults.

DOSAGE AND ADMINISTRATION: The recommended dose for vilazodone is 20 mg to 40 mg orally once daily with food. Vilazodone should be titrated, starting with an initial dose of 10 mg once daily for 7 days, followed by 20 mg once daily for an additional 7 days, and then increase to 40 mg once daily with food. No dose adjustment is recommended on the basis of age and gender.

CONTRAINDICATION: Known hypersensitivity to Vilazodone or to any of the excipients. Vilazodone must not be used concomitantly in patients taking MAOIs or in patients who have taken Monoamine Oxidase Inhibitors (MAOIs) within the preceding 14 days due to the risk of serious, sometimes fatal, drug interactions with serotonergic drugs.

WARNINGS & PRECAUTIONS: Clinical Worsening and Suicide Risk, Seizures, Abnormal Bleeding, Activation of Mania/Hypomania, Discontinuation of Treatment with Vilazodone, Hyponatremia and Angle Closure Glaucoma.

DRUG INTERACTION: Central Nervous System (CNS)-Active Agents, Monoamine Oxidase Inhibitors (MAOI), Serotonergic Drugs, Drugs that Interfere with Hemostasis (e.g., NSAIDs, Aspirin, and Warfarin), and inhibitors of CYP3A4 (e.g., ketoconazole), CYP3A4 inducers (e.g., carbamazepine), inhibitors of CYP2C19, drugs metabolized by CYP1A2, CYP2C9, CYP2D6, CYP3A4 or CYP2C19, drugs metabolized by CYP2C8, triptans and alcohol.

ADVERSE REACTIONS: Hyponatremia, angle closure glaucoma, activation of mania/hypomania, diarrhea, nausea, dry mouth, vomiting, dyspepsia, flatulence, gastroenteritis, dizziness, somnolence, paresthesia, tremor, insomnia, abnormal dreams, libido decreased, restlessness, fatigue, feeling jittery, cardiac disorders, palpitations, arthralgia, delayed ejaculation, erectile dysfunction, increased appetite, decreased libido, hallucinations, suicide attempt and suicidal ideation.

MARKETED BY:

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IN/ VALZ 20 mg and 40 mg/Dec-20/03/ABPI

(Additional information is available on request)