

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]

Suicidal thoughts and Behaviour

- Antidepressants increase the risk of suicidal thoughts and behaviours in patients aged 24 years and younger.
- Monitor for clinical worsening and emergence of suicidal thoughts and behaviours
- Safety and effectiveness of Vilazodone hydrochloride have not been established in paediatric patients.

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: 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: Diarrhea, nausea, dry mouth, vomiting, dyspepsia, flatulence, and gastroenteritis, dizziness, somnolence, paresthesia, and tremor; insomnia, abnormal dreams, decreased libido, restlessness, abnormal orgasm, fatigue and feeling jittery, palpitations,

arthralgia, delayed ejaculation, erectile dysfunction, increased appetite, decreased libido, abnormal orgasm, delayed ejaculation, erectile dysfunction, sexual dysfunction, abnormal orgasm, and sexual dysfunction, ventricular extrasystoles, vision blurred, dry eye; infrequent: cataracts, infrequent: feeling abnormal, sedation, migraine; infrequent: dysgeusia, panic attack, mania, hyperhidrosis, and night sweats.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/VALZ 20, 40mg /FEB 2026/04/ABPI

(Additional information is available on request)