TORVOX

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **TORVOX** [Vortioxetine Tablets (5 mg, 10 mg, 20 mg)]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION*:* The mechanism of action of vortioxetine is thought to be related to its direct modulation of serotonergic receptor activity and inhibition of the serotonin (5-HT) transporter. Nonclinical data indicate that vortioxetine is a 5-HT3, 5-HT7, and 5-HT1D receptor antagonist, 5-HT1B receptor partial agonist, 5-HT1A receptor agonist and inhibitor of the 5-HT transporter, leading to modulation of neurotransmission in several systems, including predominantly the serotonin but probably also the norepinephrine, dopamine, histamine, acetylcholine, GABA and glutamate systems.

INDICATIONS It is indicated for the treatment of major depressive disorder in adults.

DOSAGE AND ADMINISTRATION: The starting and recommended dose of Vortioxetine is 10 mg vortioxetine once daily in adults less than 65 years of age. Vortioxetine is for oral use. The film-coated tablets can be taken with or without food.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. Concomitant use with nonselective monoamine oxidase inhibitors (MAOIs) or selective MAO-A inhibitors.

WARNINGS & PRECAUTIONS: Vortioxetine is not recommended in children and should not be used in adolescents with MDD due to lack of efficacy and increased risk of suicidal ideation and aggression. All patients, especially those under 25 years, should be closely monitored for suicidal thoughts, behavioral changes, seizures, serotonin syndrome, mania, and bleeding, particularly early in treatment or after dose changes. Caution is required in the elderly, and in patients with glaucoma, hyponatraemia, or renal/hepatic impairment, and treatment should be discontinued if serious adverse reactions occur.

DRUG INTERACTIONS: Vortioxetine is primarily metabolised by CYP2D6, with contributions from CYP3A4/5 and CYP2C9, and has significant interaction potential. It is contraindicated with MAOIs due to the risk of serotonin syndrome and should be used cautiously with other serotonergic drugs, St. John's wort, seizure-threshold–lowering medicines, and ECT. Strong CYP2D6 inhibitors increase vortioxetine exposure (dose reduction may be needed), while CYP inducers like rifampicin markedly reduce levels (dose adjustment may be required); CYP3A4/2C9 inhibitors cause only modest increases. Vortioxetine has minimal effect on other drugs, including oral contraceptives and warfarin, though bleeding risk may increase with anticoagulants/antiplatelets, caution is advised with lithium or tryptophan, alcohol is not recommended, and false-positive methadone urine screens may occur.

ADVERSE REACTIONS: Dizziness, serotonin syndrome headache, mydriasis, flushing, hemorrhages, nausea, diarrhea, constipation, vomiting, Pruritus, including pruritus generalized Hyperhidrosis, Night sweats, Angioedema, Urticaria Rash.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/TORVOX (5 mg, 10 mg, 20 mg)/Jul-2023/01/PI

(Additional information is available on request)