Voxigain

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

Abbreviated Prescribing information for Vortioxetine (Vortioxetine Tablets (5 mg + 10 mg + 20 mg)

[Please refer the complete prescribing information for details]

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. This multimodal activity is considered responsible for the antidepressant and anxiolytic-like effects, and the improvement of cognitive function, learning and memory observed with vortioxetine in animal studies. However, the precise contribution of the individual targets to the observed pharmacodynamic profile remains unclear and caution should be applied when extrapolating animal data directly to man.

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. Depending on individual patient response, the dose may be increased to a maximum of 20 mg vortioxetine once daily or decreased to a minimum of 5 mg vortioxetine once daily. After the depressive symptoms resolve, treatment for at least 6 months is recommended for consolidation of the antidepressive response. The lowest effective dose of 5 mg vortioxetine once daily should always be used as the starting dose in patients ≥ 65 years of age. Caution is advised when treating patients ≥ 65 years of age with doses higher than 10 mg vortioxetine once daily for which data are limited. Depending on individual patient response, a lower dose of vortioxetine may be considered if a strong CYP2D6 inhibitor treatment. Vortioxetine tablet should be administered orally. 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 for the treatment of depression in children aged 7 to 11 years since the safety and efficacy of vortioxetine have not been established in this age group. Vortioxetine should not be used in adolescents aged 12 to 17 years with major depressive disorder (MDD) because efficacy has not been demonstrated. Patients with a history of suicide-related events or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment are known to be at greater risk of suicidal thoughts or suicide attempts and should receive careful monitoring during treatment. vortioxetine should be introduced cautiously in patients who have a history of seizures or in patients with unstable epilepsy. Treatment should be discontinued in any patient who develops seizures or for whom there is an increase in seizure frequency. Serotonin Syndrome (SS) or Neuroleptic Malignant Syndrome (NMS), potentially life-threatening conditions, may occur with vortioxetine. Vortioxetine should be used with caution in patients with a history of mania/hypomania and should be discontinued in any patient entering a manic phase. Discontinuation of vortioxetine should be considered in patients with symptomatic hyponatraemia and appropriate medical intervention should be instituted.

DRUG INTERACTIONS: Due to the risk of serotonin syndrome, vortioxetine is contraindicated in any combination with irreversible non-selective MAOIs. The combination of vortioxetine with a reversible and selective MAO-A inhibitor, such as moclobemide, is contraindicated. The combination of vortioxetine with a weak reversible and non-selective MAOI, such as the antibiotic linezolid, is contraindicated. Co-administration of medicinal products with serotonergic effect (e.g., tramadol, sumatriptan and other triptans) may lead to serotonin syndrome.

ADVERSE REACTIONS: Anaphylactic reaction, hyponatraemia, abnormal dreams, insomnia, agitation, aggression, dizziness, serotonin syndrome, mydriasis (which may lead to acute narrow angle glaucoma), flushing, haemorrhage (including contusion, ecchymosis, epistaxis, gastrointestinal or vaginal bleeding), nausea, diarrhoea, constipation, vomiting, pruritus, including pruritus generalized, night sweats, angioedema, urticaria, sexual dysfunction and rash.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/ VOXIGAIN 5, 10, 20 mg/FEB-23/01/ABPI

(Additional information is available on request)