

LEVAZEO 25

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory
Abbreviated Prescribing information for Levazeo (Levosulpiride 25mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Levosulpiride is an active isomer of sulpiride. It is D₂ receptor antagonist.

INDICATION: Levazeo is indicated for the treatment of gastro-intestinal problems like functional dyspepsia, nausea, vomiting and diabetic gastroparesis.

DOSAGE AND ADMINISTRATION: *Adults:* the recommended dosage is 1 tablet of 25 mg 3 times daily before meals.

CONTRAINDICATION: Levazeo is contraindicated in patients of pheochromocytoma, epilepsy, manic conditions. It is also contraindicated in pregnancy and lactation and in patients with concomitant prolactin dependent tumor. Also it is contraindicated in the patients with known hypersensitivity to levosulpiride or any other ingredients of the formulation. Association with levodopa.

WARNINGS & PRECAUTIONS: Dosage reduction may require in occurrence of extrapyramidal reactions. Caution is advised when administering the drug in patients with convulsion, cerebrovascular events, prolongations of QTc interval, porphyria, cardiac insufficiency, manic conditions, in elderly patients and in patients taking neuroleptics. It should not be used when gastrointestinal stimulation of motility can be harmful. Levosulpiride may cause drowsiness hence caution should be advised while driving and operating machinery. Caution required for neuroleptic malignant syndrome (NMS).

DRUG INTERACTIONS: Interacts with levopoda, neuroleptics, alcohol, beta blockers, calcium channel blockers (verapamil, diltiazem), clonidine, digitalis, hypokalaemic diuretics, stimulant laxatives, IV amphoterecin B, glucocorticoids, tetracosetides, Class Ia and Class III antiarrhythmic agents, pimozone, haloperidol; methadone, imipramine antidepressants; lithium, cisapride, thioridazine, IV erythromycin, halofantrine, pentamidine, CNS depressants, ropinirole, antacids/sucralfate, lithium.

ADVERSE REACTIONS: Postural hypotension, NMS, QT interval prolongation, ventricular arrhythmias/tachycardia, torsade de pointes, hyperprolactinaemia and related disorders, weight gain, increase in hepatic enzymes, sedation, drowsiness, insomnia, extrapyramidal symptoms/disorders, parkinsonism and related symptoms, acute dyskinesia, dystonia, akathisia, maculo-papular rash, venous thromboembolism, pulmonary embolism, deep vein thrombosis.

MARKETED BY:



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IN/LEVAZEO 25 mg/FEB 2015/01/AbPI

(Additional information is available on request)