

LEVAZEO

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory
Abbreviated Prescribing information for Levazeo (Levosulpiride 50mg, 100mg 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. Blockade of centrally located DA autoreceptors at lower doses and blockade of post synaptic DA receptors at higher doses seems to contribute to the antidepressant and antipsychotic effects of levosulpiride.

INDICATION: Levazeo is indicated for the treatment of schizophrenia and depression in adults.

DOSAGE AND ADMINISTRATION: For schizophrenia: The recommended dose for adults is 2-3 tablets of levosulpiride 100mg daily in divided doses. Maintenance dose of levosulpiride is 3 tablets of 50 mg in divided doses. For depression: recommended dosage is 2-3 tablets of levosulpiride 50mg daily in divided doses. Caution is advised when used in the elderly patients. Dose adjustments have been suggested in renal insufficiency.

CONTRAINDICATION: In patients of pheochromocytoma and epilepsy, in pregnancy and lactation, and in patients with concomitant prolactin dependent tumor, patients with known hypersensitivity to levosulpiride or any other ingredients of the formulation and association with levodopa.

WARNINGS & PRECAUTIONS: Associated with development neuroleptic malignant syndrome, dosage reduction may require in occurrence of extrapyramidal reactions, not be used when gastrointestinal stimulation of motility can be harmful, drowsiness, Caution should be exercised in convulsion, in the manic phase of manic depressive psychosis, cardiac insufficiency, cerebrovascular events, factors that may predispose QTc interval prolongation and with other neuroleptics.

DRUG INTERACTIONS: Interacts with levopoda, neuroleptics, alcohol, beta blockers, calcium channel blockers (verapamil, diltiazem), clonidine, digitalis, hypokalaemic diuretics, stimulant laxatives, IV amphoterecin B, quinidine, dysopyramide, sotalol, amiodarone, glucocorticoids, tetracosetides, Class Ia and Class III antiarrhythmic agents, pimozide, haloperidol; methadone, imipramine antidepressants; lithium, cisapride, thioridazine, IV erythromycin, halofantrine, pentamidine, CNS depressants, ropinirole, antacids/sucralfate, lithium, narcotics, analgesics, sedative H₁ antihistamines, barbiturates, benzodiazepines, other anxiolytics, antacids and sucralfate.

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, insomnia, extrapyramidal symptoms/disorders, parkinsonism and related symptoms, galactorrhoea, amenorrhoea, gynaecomastia, erectile dysfunction, maculo-papular rash, acute dyskinesia, dystonia, akathisia, maculo-papular rash, venous thromboembolism, pulmonary embolism and deep vein thrombosis.

MARKETED BY:



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(Additional information is available on request)