LEVAZEO SR 75

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

Abbreviated Prescribing information for LEVAZEO SR 75 (Levosulpiride 75 mg Extended Release tablet) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Levosulpiride selectively blocks D2 receptors at the submucosal and myenteric plexus peripheral level. Antidopaminergic properties of levosulpiride at D2 receptors of the chemoreceptor trigger zone is responsible for anti emetic property.

INDICATION: For the treatment of different gastrointestinal problems like functional dyspepsia, nausea, vomiting and diabetic gastroparesis.

DOSAGE AND ADMINISTRATION: In adults, the recommended dosage is 1 tablet of 75 mg once daily before meals.

CONTRAINDICATION: Hypersensitivity to the drug or any other excipients of the formulation, Pheochromocytoma as it can cause hypertensive attack probably due to release of catecholamine from tumor, Epilepsy, Concomitant prolactin dependent tumors like pituitary gland prolactinomas and breast cancer, Pregnancy and lactation, Association with levodopa, In manic conditions and in the manic stages of manic depressive psychoses.

WARNINGS & PRECAUTIONS: Extrapyramidal reactions, mainly akathisia, and for that dosage reduction warranted. Increased motor agitation at higher dosages Neuroleptic malignant syndrome, a potentially fatal complication has been reported. In such an event Levosulpiride, should be discontinued. Patients with a convulsion Prolongations of QTc interval or factors that may predispose OTc interval prolongation (Bradycardia, hypokalemia, congenital QTc prolongation, decreased intracardiac conduction) Patients with a history cerebrovascular events (stroke, Venous thromboembolism). Elderly: The dose should be reduced if there is evidence of renal impairment.

DRUG INTERACTION: Levodopa: reciprocal antagonism of effects between levopoda and neuroleptics. Alcohol: alcohol enhances the sedative effects of neuroleptics. Bradycardia inducing medications: Beta blockers, calcium channel blockers (verapamil, diltiazem), clonidine, and digitalis. Medications which induce electrolyte imbalance (particularly hypokalemia): hypokalaemic diuretics, stimulant laxatives, IV amp hoterecin B, glucocorticoids, and tetracosectides. Antihypertensive agents: antihypertensive effect and possibility of enhanced postural hypotension. Antacids or sucralfate: The absorption of sulpiride is decreased after co-administration. Lithium increases the risk of extrapyramidal side effects; Sulpiride may reduce the effectiveness of ropinorole.

ADVERSE REACTIONS: Postural hypotension, QT interval prolongation and ventricular arrhythmias, Hyperprolactinaemia, Neuroleptic malignant syndrome, Weight gain, Increase in hepatic enzymes, Sedation or drowsiness, Insomnia, Parkinsonism and related symptoms: tremor, hypertonia, hypokinesia, hypersalivation, Acute dyskinesia, dystonia, Akathisia, Tardive dyskinesia, Convulsions, Disorders related to hyperprolactinaemia, Galactorrhoea, Amenorrhoea, Gynaecomastia, Breast enlargement and breast pain, Orgasmic dysfunction, erectile dysfunction,, change in libido, Maculo-papular rash, Venous thromboembolism, pulmonary embolism and deep vein thrombosis.

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(Additional information is available on request)