LEVAZEO INJ

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory Abbreviated Prescribing information for Levazeo Inj (Levosulpiride Injection) [Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>]

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

INDICATION: It is indicated for the treatment of different gastrointestinal problems like functional dyspepsia, nausea, vomiting and diabetic gastro-paresis when oral therapy is not advisable/feasible.

DOSAGE AND ADMINISTRATION: (for IM or IV use only) Initiate levosulpiride injection only in case when oral administration is difficult. Administer Levazeo injection 2 to 3 times till symptoms disappear. Patient should be switched to oral therapy as soon as possible.

CONTRAINDICATION: Levazeo injection is contraindicated in patients of pheochromocytoma, epilepsy and mania. 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.

WARNINGS & PRECAUTIONS: Caution is advices when administering the drug in patients with cerebrovascular events, cardiac insufficiency, porphyria and in elderly patients. 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. Sulpiride should be avoided in renal impaired patients.

DRUG INTERACTIONS: It can interact with other centrally acting drugs. It can potentiate the cognitive and motor effect of alcohol. Anticholinergic drugs, narcotics and analgesic drugs antagonize the effect of levosulpiride.

ADVERSE REACTIONS: amenorrhea, gynecomastia, galactorrhea, hyperprolactinemia, changes in libido, reversible effects on function of hypothalamic pituitary gonadal axis, drowsiness/ sedation, breast tenderness, hoarseness, abdominal cramp, menstrual changes/metrorrhagia, weight gain, galactorrhoea, hypersalivation, sleeplessness, constipation, vertigo and/or fatigue, headache, dry mouth, increased motor activity, agitation, sedation, mental confusion, hiccups, hot flushes, diarrhea and visual disorder, sleep disturbances, overstimulation, agitation and hypotension.

MARKETED BY: TORRENT PHARMACEUTICALS LTD. Torrent house, Off Ashram road, Ahmedabad - 380009, INDIA

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