

ILOBRIL

For the use of a psychiatrist or a Hospital or a Laboratory only

Abbreviated Prescribing information for ILOBRIL (Iloperidone 1 mg, 2 mg, 4 mg, 6 mg and 8 mg tablet) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Iloperidone is a psychotropic agent which action is proposed to be mediated through a combination of dopamine type 2 (D₂) and serotonin type 2 (5-HT₂) antagonisms.

INDICATIONS: For the acute treatment of adults with schizophrenia.

DOSAGE AND ADMINISTRATION: The recommended starting dose for iloperidone tablets is 1 mg twice daily. Increases to reach the target dose range of 6-12 mg twice daily may be made with daily dosage adjustments to 2 mg twice daily, 4 mg twice daily and 6 mg twice daily, on days 2, 3 and 4 respectively. The maximum recommended dose is 12 mg twice daily (24 mg/day). It is recommended that the initiation titration schedule be followed whenever patients have had an interval off iloperidone of more than 3 days.

CONTRAINDICATION: In individuals with a known hypersensitivity reaction to the product. Reactions have included pruritus and urticaria.

WARNINGS & PRECAUTIONS: Increased risk of death in elderly patients with dementia-related psychosis, QT prolongation when used in combination with drugs known to prolong QTc, drugs that inhibit iloperidone metabolism and in patients with reduced activity of CYP2D6, risk of Neuroleptic Malignant Syndrome (NMS), tardive dyskinesia, hyperglycemia and diabetes mellitus, weight gain, seizures, orthostatic hypotension and syncope, leukopenia, neutropenia and agranulocytosis, hyperprolactinemia, disruption of body temperature regulation, dysphagia, suicide, priapism, cognitive and motor impairment.

DRUG INTERACTIONS: Interacts with QT prolonging drugs, ketoconazole, fluoxetine, paroxetine and dextromethorphan when used concomitantly.

ADVERSE REACTIONS: Arthralgia, fatigue, musculoskeletal stiffness, anemia, iron deficiency anemia, palpitations, arrhythmia, atrioventricular block first degree, cardiac failure, hypotension, vertigo, tinnitus, hypothyroidism, conjunctivitis, vision blurred, dry eye, blepharitis, eyelid edema, eye swelling, lenticular opacities, cataract, hyperemia, nausea, dry mouth, diarrhea, abdominal discomfort, gastritis, salivary hypersecretion, fecal incontinence, mouth ulceration, duodenal ulcer, hiatus hernia, hyperchlorhydria, lip ulceration, reflux esophagitis, stomatitis, edema, difficulty in walking, thirst, hyperthermia, cholelithiasis, weight decreased, hemoglobin decreased, neutrophil count increased, hematocrit decreased, increased appetite, dehydration, hypokalemia, fluid retention, myalgia, muscle spasms, torticollis, somnolence, extrapyramidal disorder, tremor, lethargy, paraesthesia, psychomotor hyperactivity, restlessness, amnesia, nystagmus, restless legs syndrome, restlessness, aggression, delusion, hostility, libido decreased, paranoia, anorgasmia, confusional state, mania, catatonia, panic attack, obsessive-compulsive disorder, bulimia nervosa, delirium, polydipsia psychogenic, impulse-control disorder, major depression, urinary incontinence, dysuria, pollakiuria, enuresis, nephrolithiasis, urinary retention, renal failure acute, erectile dysfunction, ejaculation failure, testicular pain, amenorrhea, breast pain, menstruation irregular, gynecomastia, menorrhagia, metrorrhagia, postmenopausal hemorrhage, prostatitis, retrograde ejaculation, nasal congestion, dyspnea, epistaxis, asthma, rhinorrhea, sinus congestion, nasal dryness, dry throat, sleep apnea syndrome, dyspnea exertional, rash, nasopharyngitis, upper respiratory tract infection.

MARKETED BY:



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(Additional information is available on request)