

THIORIL

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

Abbreviated Prescribing information for THIORIL [Thioridazine 10, 25 and 50 mg Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Thioridazine is similar to that of other phenothiazines, but is associated with minimal extrapyramidal stimulation.

INDICATION: Thioridazine hydrochloride tablets are indicated for the management of schizophrenic patients who fail to respond adequately to treatment with other antipsychotic drugs.

DOSAGE AND ADMINISTRATION: *For adults* usual starting dose for schizophrenic patients is 50 mg to 100 mg three times a day, with a gradual increment to a maximum of 800 mg daily. The total daily dosage ranges from 200 mg to 800 mg, divided into two to four doses. *For pediatric patients* starting dose 0.5 mg/kg/day can be given in divided doses and maximum up to 3 mg/kg/day.

CONTRAINDICATION: It is contra-indicated in patients with clinically significant cardiac disorders, QTc interval prolongation; history of ventricular arrhythmias or Torsades de Pointes; bradycardia or 2nd or 3rd degree heart block; family history of QTc interval prolongation; uncorrected hypokalaemia or hypomagnesaemia. Patients taking other therapeutic agents known to be either substrates or the inhibitors of cytochrome P450 2D6; hypersensitivity to thioridazine HCl or other phenothiazines, thioridazine base or any of the other excipients; comatose states, dementia, severe depression of the CNS, history of serious hematological conditions.

WARNINGS & PRECAUTIONS: Patients with dementia related psychosis especially in elderly due to increased risk of mortality; potential for proarrhythmic effects, tardive dyskinesia, hypersensitivity reaction to the thioridazine or any other excipients of the tablets.

DRUG INTERACTIONS: Potentiates effect of CNS depressants (anesthetics, opiates, alcohol), Drugs which are inducers or inhibitors of P450 2D6, Drugs affecting the QTc prolongation, it interacts with atropine, phosphorus insecticides.

ADVERSE REACTIONS: Nocturnal confusion, hyperactivity, lethargy, psychotic reactions, restlessness, headache, pseudoparkinsonism other extrapyramidal symptoms, dryness of mouth, blurred vision, constipation, nausea, vomiting, diarrhea, nasal stuffiness, pallor, galactorrhea, breast engorgement, amenorrhea, inhibition of ejaculation, peripheral edema, dermatitis, skin eruptions, dose related prolongation of the QTc interval, torsades de pointes type arrhythmias, ventricular tachycardia, sudden death, NMS, urinary disturbances, endocrine disturbances, extrapyramidal reactions, tardive dyskinesia, allergic reactions, blood dyscrasias, severe cutaneous reactions.

MARKETED BY:



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(Additional information is available on request)