JOLIVEL

For the use of Psychiatrists Only

Abbreviated Prescribing information for Jolivel (Opipramol Dihydrochloride 50,100mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com

PHARMACOLOGICAL PROPERTIES: - Opipramol has high affinity for the sigma binding sites (type 1 and type 2) and histamine antagonist receptors of type 1 and acts as sedative, anxiolytic and mood-lifting agent. **INDICATION:** For the treatment of generalised anxiety disorder (GAD) and somatic disturbances. **DOSAGE AND ADMINISTRATION:** The dosage in adults should be usually 1-2 tablets per day (in the morning and in the evening) according. The dosage may depend on the efficacy and tolerability up to once daily 50 mg -100 mg and it can be reduced or increased up to 3 times daily. Children older than 6 years should receive 3 mg Opipramol/kg body weight. Since the experience with Opipramol tablets is limited in the pediatric dosage, this recommendation is only a framework directive. Opipramol tablets should be taken with some liquid (water, fruit juice). Since the effect of tablets Opipramol not abruptly occurs in appearance and gradually occurs, the drug should be taken regularly for at least 2 weeks. Average treatment duration of 1-2 months is advisable. **CONTRAINDICATION:** In patients hypersensitive to opipramol dihydrochloride, propyl 4-hydroxybenzoate, methyl 4- hydroxy benzoate or any of the other ingredients, acute alcohol, sedatives, analgesics and psychotropic intoxication, acute urinary retention, acute delirium, untreated narrow angle glaucoma, prostatic hypertrophy with urinary retention, paralytic ileus, pre-existing higher-grade av block or diffuse supraventricular or ventricular conduction disturbances, combination with MAO inhibitors. **WARNINGS & PRECAUTIONS**: Opipramol tablets should not be used in patients with prostate, liver, kidney diseases, brain damage of different etiologies, cerebrovascular insufficiencies, cardiac pre damage especially conduction damages, epilepsy and alcoholism. Patients with rare hereditary problems such as galactose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take Opipramol tablets. **DRUG INTERACTIONS:** Fluoxetine and fluvoxamine may thus lead to an increase in the plasma concentrations of tricyclic psychotropic drugs and side effects; hence if necessary its dosage should be reduced. The combination of opipramol with alcohol can cause drowsiness. MAO Inhibitors should be discontinued at least 14 days prior to treatment with opipramol tablets. Appropriate dose adjustments should be made with beta-blockers (eg, propranolol), antiarrhythmics class Ic, barbiturates, anticonvulsants and antipsychotic drugs (e.g., haloperidol, risperidone). **ADVERSE REACTIONS:** Fatigue, dry, mouth, stuffy nose, dizziness, drowsiness, micturition disorders, accommodation, disturbances, tremor, weight gain, thirst, agitation, headache, paresthesia, especially in the elderly confusion and delirium, especially when abrupt withdrawal, restlessness, sweating, insomnia, seizures, motor disorders (akathisia, dyskinesia), ataxia, polyneuropathy, glaucoma seizures, anxiety, allergic skin reactions (rash, urticaria), edema, baldness, ejaculation disorders, erectile impotence, galactorrhea, urinary retention, constipation, stomach discomfort, dysgeusia, paralytic ileus, particularly when abrupt withdrawal of a longterm, high-dose therapy nausea and vomiting, transient increases in liver enzyme activities, severe hepatic impairment, after long-term treatment jaundice and chronic liver damage, tachycardia, palpitations, collapse states, conduction disturbances, reinforcing an existing heart failure, leucopenia and agranulocytosis.

MARKETED BY:

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(Additional information is available on request)