

PALIDO-OD

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

Abbreviated Prescribing information for **PALIDO-OD** [Paliperidone 1.5mg, 3mg, 6mg and 9mg film coated extended release tablet] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: The mechanism of action of paliperidone, as with other drugs having efficacy in schizophrenia, is unknown, but it has been proposed that the drug's therapeutic activity in schizophrenia is mediated through a combination of central dopamine Type 2 (D2) and serotonin Type 2 (5HT2A) receptor antagonism. Paliperidone is also active as an antagonist at $\alpha 1$ and $\alpha 2$ adrenergic receptors and H1 histaminergic receptors, which may explain some of the other effects of the drug.

INDICATION: Indicated for the acute and maintenance treatment of schizophrenia.

DOSAGE AND ADMINISTRATION: The starting dose of Palido OD Tablets is 3 mg once daily, administered in the morning. Dose increases above 3 mg/day should be made only after clinical assessment and generally should occur at intervals of 5 days with increment of 3mg/day. The maximum recommended dose is 12 mg/day. It can be taken with or without food.

CONTRAINDICATION: contraindicated in patients with a known hypersensitivity to paliperidone, risperidone, or to any components in the Paliperidone ER formulation.

WARNINGS & PRECAUTIONS: Use cautiously and stop the Palido OD in patients with QT prolongation, neuroleptic malignant syndrome, tardive dyskinesia, hyperglycemia and diabetes mellitus, orthostatic hypotension and syncope, seizures, hyperprolactinemia, dysphagia, suicide, potential for cognitive and motor impairment, priapism, body temperature regulation, antiemetic effect, concomitant medication, alcohol and with concomitant illness.

DRUG INTERACTIONS: Levodopa and other dopamine agonists, carbamazepine, paroxetine, divalproex sodium extended-release tablets and lithium.

ADVERSE REACTIONS: Upper respiratory tract infection, nasopharyngitis, weight increased, increased appetite, agitation, dystonia, parkinsonism, dysarthria, akathisia, dyskinesia, extrapyramidal disorder, tremor, dizziness, sedation, somnolence, vision blurred, headache, sinus tachycardia, tachycardia, orthostatic hypotension, cough, pharyngeal pain, nasal congestion, vomiting, abdominal discomfort/ abdominal pain upper, stomach discomfort, nausea, dyspepsia, dry mouth, constipation, arthralgia, back pain, pain in extremity, asthenia and fatigue.

MARKETED BY:



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IN/PALIDO-OD 1.5,3,6,9mg film /Oct-2015/01/ABPI

(Additional information is available on request)