RESPIDON

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

Abbreviated Prescribing information for **RESPIDON** [Risperidone Tablets 1mg, 2mg, 3mg and 4mg] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: RESPIDON is a selective monoaminergic antagonist with unique properties. It has a high affinity for serotoninergic 5-HT2 and dopaminergic D2 receptors. RESPIDON binds also to alpha1-adrenergic receptors, and, with lower affinity, to H1-histaminergic and alpha 2 adrenergic receptors. RESPIDON has no affinity for cholinergic receptors. Although RESPIDON is a potent D2 antagonist, which is considered to improve the positive symptoms of schizophrenia, it causes less depression of motor activity and induction of catalepsy than classical antipsychotics. Balanced central serotonin and dopamine antagonism may reduce extrapyramidal side effect liability and extend the therapeutic activity to the negative and affective symptoms of schizophrenia.

DOSAGE AND ADMINISTRATION: Adults: administered once or twice daily. Initial dosing is generally 2 mg/day. Adolescents: should be initiated at 0.5 mg once daily, administered as a single-daily dose in either the morning or evening.

CONTRAINDICATION: Contraindicated in patients with a known hypersensitivity to the active ingredients or to any of the excipients of the product.

WARNINGS & PRECAUTIONS: Use cautiously and stop the risperidone in elderly patients with dementia-related psychosis, cerebrovascular adverse reactions, including stroke, in elderly patients with dementia-related psychosis, neuroleptic malignant syndrome (NMS), tardive dyskinesia, hyperglycemia and diabetes mellitus, hyperprolactinemia, weight gain, orthostatic hypotension, leukopenia, neutropenia, and agranulocytosis, potential for cognitive and motor impairment, seizures, dysphagia, priapism, thrombotic thrombocytopenic purpura (TTP), body temperature regulation, antiemetic effect, suicide and use in patients with concomitant illness.

DRUG INTERACTIONS: Centrally-acting drugs and alcohol, drugs with hypotensive effects, levodopa and dopamine agonists, amitriptyline, cimetidine and ranitidine, clozapine, lithium, valproate, digoxin, drugs that inhibit CYP2D6 and other CYP isozymes, erythromycin and carbamazepine and other enzyme inducers.

ADVERSE REACTIONS: Blood prolactin increased, weight increased, tachycardia, neutropenia, anaemia, thrombocytopenia, parkinsonism, headache, akathisia, dizziness, tremor, dystonia,

somnolence, sedation, lethargy, dyskinesia, unresponsive to stimuli, loss of consciousness, syncope, depressed level of consciousness, cerebrovascular accident, transient ischaemic attack, dysarthria, disturbance in attention, hypersomnia, dizziness postural, balance disorder, tardive dyskinesia, speech disorder, coordination abnormal, hypoaesthesia, dysgeusia, vision blurred, conjunctivitis, ocular hyperaemia, eye discharge, eye swelling, dry eye, lacrimation increased, photophobia, dyspnoea, epistaxis, cough, nasal congestion, pharyngolaryngeal pain, vomiting, diarrhoea, constipation, nausea, abdominal pain, dyspepsia, dry mouth, stomach discomfort, enuresis, rash, erythema, arthralgia, back pain, pain in extremity, increased appetite, decreased appetite, pneumonia, influenza, bronchitis, upper respiratory tract infection, urinary tract infection, pyrexia, fatigue, peripheral oedema, asthenia, chest pain, hypersensitivity and insomnia.

MARKETED BY:



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IN/ RESPIDON/1, 2, 3, 4 mg/MAY-2021/02/ABPI

(Additional information is available on request)