

ARIP 5

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

Abbreviated Prescribing information for **ARIP 5** [Aripiprazole Tablets I.P. 5mg] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Aripiprazole's efficacy in schizophrenia and Bipolar I Disorder is mediated through a combination of partial agonism at dopamine D2 and serotonin 5HT1a receptors and antagonism of serotonin 5HT2a receptors. Interaction with receptors other than dopamine and serotonin subtypes may explain some of the other clinical effects of aripiprazole. **INDICATION:** Aripiprazole is indicated for the treatment of schizophrenia. **DOSAGE AND ADMINISTRATION:** In adults the recommended starting dose for aripiprazole is 10 or 15 mg/day with a maintenance dose of 15 mg/day administered on a once-a-day schedule without regard to meals. In adolescents aged 15 years and older: the recommended dose for aripiprazole is 10 mg/day administered on a once-a-day schedule without regard to meals. **CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients listed in its composition. **WARNINGS & PRECAUTIONS:** Close supervision of high-risk patients should accompany antipsychotic therapy. Caution should be exercised in patients with cardiovascular disease, cerebrovascular disease, conditions which would predispose patients to hypotension or hypertension, including accelerated or malignant. It should be used with caution in patients with a family history of QT prolongation. If signs and symptoms of tardive dyskinesia appear in a patient on aripiprazole, dose reduction or discontinuation should be considered. Dose reduction and close clinical monitoring should be considered, if signs and symptoms of other EPS appear in a patient taking aripiprazole. As with other medicinal products, hypersensitivity reactions, characterized by allergic symptoms, may occur with aripiprazole. Caution should be taken while taking aripiprazole in conditions such as neuroleptic malignant syndrome, seizure, diabetes mellitus, weight gain, dysphagia and in patients with attention deficit hyperactivity disorder. patients should be cautioned about operating hazardous machines, including motor vehicles, until they are reasonably certain that aripiprazole does not affect them adversely. **DRUG INTERACTIONS:** Caution should be used, if aripiprazole is administered concomitantly with medicinal products known to cause QT prolongation or electrolyte imbalance, it may interact with quinidine and other *CYP2D6* inhibitors, ketoconazole and *CYP3A4* inhibitors, carbamazepine and other *CYP3A4* inducers. **ADVERSE REACTIONS:** Leukopenia, neutropenia, thrombocytopenia, allergic reaction (e.g. anaphylactic reaction, angioedema including swollen tongue, tongue edema, face edema, pruritus, or urticaria), hyperglycemia, diabetes mellitus, diabetic ketoacidosis, diabetic, hyperosmolar coma, weight gain, weight decreased, anorexia, hyponatremia, agitation, nervousness, pathological gambling, suicide attempt, suicidal ideation, completed suicide, speech disorder, Neuroleptic Malignant Syndrome (NMS), grand mal convulsion, serotonin syndrome, QT prolongation, ventricular arrhythmias, sudden unexplained death, cardiac arrest, torsades de pointes, bradycardia, syncope, hypertension, venous thromboembolism (including pulmonary embolism and deep vein thrombosis), oropharyngeal spasm, laryngospasm, aspiration pneumonia, pancreatitis, dysphagia, abdominal discomfort, stomach discomfort, Diarrhea, hepatic failure, jaundice, hepatitis, increased Alanine Aminotransferase (ALT), increased Aspartate Aminotransferase (AST), increased Gamma Glutamyl Transferase (GGT), increased alkaline phosphatase, rash, photosensitivity reaction, alopecia, hyperhidrosis, rhabdomyolysis, myalgia, stiffness, urinary incontinence, urinary retention, drug withdrawal syndrome neonatal, priapism, temperature regulation disorder (e.g. hypothermia, pyrexia), chest pain, peripheral oedema, increased creatine phosphokinase, blood glucose increased, blood glucose fluctuation and glycosylated haemoglobin increased

MARKETED BY:



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(Additional information is available on request)