

Medical Practitioner or a Hospital or a Laboratory Only
Abbreviated Prescribing information for ARIP MT [Aripiprazole
5mg/10mg/15mg/20mg/30mg Tablets]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: The mechanism of action of aripiprazole in schizophrenia or bipolar mania is unknown. However, the efficacy of aripiprazole could be mediated through a combination of partial agonist activity at D2 and 5-HT1A receptors and antagonist activity at 5-HT2A receptors.

INDICATION: For the treatment of schizophrenia.

DOSAGE AND ADMINISTRATION: Adult: Dose 10 or 15mg daily without regards to meal. Dosage increases should generally not be made before 2 weeks, the time needed to achieve steady state. Adolescent: The recommended target dose of aripiprazole is 10 mg/day. Dosage adjustments are recommended in patients who are known CYP2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors or strong CYP3A4 inducers.

CONTRAINDICATION: Aripiprazole is contraindicated in patients with a history of a hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

WARNINGS & PRECAUTIONS: Elderly patients with dementia related psychosis, cerebrovascular adverse events with stroke, clinical worsening of depression and suicide risk, underlying bipolar disorder, neuroleptic malignant syndrome, tardive dyskinesia, metabolic changes (hyperglycemia/diabetes mellitus, dyslipidemia, weight gain), orthostatic hypotension, leukopenia, neutropenia, and agranulocytosis, seizures/convulsions, potential for cognitive and motor impairment, body temperature regulation, dysphagia, patients with systemic illnesses.

DRUG INTERACTIONS: Centrally acting drugs, alcohol, certain anti-hypertensive, agents affecting CYP3A4 and CYP2D6, ketoconazole and other CYP3A4 inhibitors, quinidine and other CYP2D6 inhibitors, carbamazepine and other CYP3A4 inducers.

ADVERSE REACTIONS: Dose related AEs are somnolence, insomnia, rigidity and headache. Extrapyrimal symptoms, weight gain, ECG changes, hypertension, tachycardia, hypotension, bradycardia, palpitation, hemorrhage, myocardial infarction, prolonged QT interval, cardiac arrest, atrial fibrillation, heart failure, AV block, myocardial ischemia, phlebitis, deep vein thrombosis, angina pectoris, extrasystoles, vasovagal reaction, cardiomegaly, atrial flutter, thrombophlebitis, anorexia, nausea, vomiting, increased appetite, gastroenteritis, dysphagia, flatulence, gastritis, tooth caries, gingivitis, hemorrhoids, gastroesophageal reflux, gastrointestinal hemorrhage, periodontal, tongue edema, fecal incontinence, colitis, rectal hemorrhage, stomatitis, mouth ulcer, cholecystitis, fecal impaction, oral moniliasis, cholelithiasis, eructation, intestinal obstruction, esophagitis, gum hemorrhage, glossitis, hematemesis, melena, duodenal ulcer, cheilitis, hepatitis, hepatomegaly, pancreatitis, intestinal perforation, hypothyroidism, goiter, hyperthyroidism, ecchymosis, anemia, hypochromic anemia, leukopenia, leukocytosis, lymphadenopathy, thrombocytopenia; eosinophilia, thrombocythemia, macrocytic anemia, weight loss, creatine phosphokinase increased, dehydration, edema, hypercholesteremia, hyperglycemia, hypokalemia, diabetes

mellitus, SGPT increased, hyperlipemia, hypoglycemia, thirst, BUN increased, hyponatremia, SGOT increased, alkaline phosphatase increased, iron deficiency anemia, creatinine increased, bilirubinemia, lactic dehydrogenase increased, obesity; hyperkalemia, gout, hypernatremia, cyanosis, hyperuricemia, hypoglycemic reaction, muscle cramp; arthralgia, bone pain, myasthenia, arthritis, arthrosis, muscle weakness, spasm, bursitis; rhabdomyolysis, tendonitis, tenosynovitis, rheumatoid arthritis, myopathy, depression, nervousness, increased salivation, hostility, suicidal thought, manic reaction, abnormal gait, confusion, cogwheel rigidity; Infrequent-dystonia, twitch, impaired concentration, paresthesia, vasodilation, hypesthesia, extremity tremor, impotence, bradykinesia, decreased libido, panic attack, apathy, dyskinesia, hypersomnia, vertigo, dysarthria, tardive dyskinesia, ataxia, impaired memory, stupor, increased libido, amnesia, cerebrovascular accident, hyperactivity, depersonalization, hypokinesia, restless leg, myoclonus, dysphoria, neuropathy, increased reflexes, slowed thinking, hyperkinesia, hyperesthesia, hypotonia, oculogyric crisis; delirium, euphoria, buccoglossal syndrome, akinesia, blunted affect, decreased consciousness, incoordination, cerebral ischemia, decreased reflexes, obsessive thought, intracranial hemorrhage, dyspnea, pneumonia; asthma, epistaxis, hiccup, laryngitis; hemoptysis, aspiration pneumonia, increased sputum, dry nasal passages, pulmonary edema, pulmonary embolism, hypoxia, respiratory failure, apnea, dry skin, pruritis, sweating, skin ulcer; acne, vesiculobullous rash, eczema, alopecia, psoriasis, seborrhea; maculopapular rash, exfoliative dermatitis, urticarial, conjunctivitis, ear pain; dry eye, eye pain, tinnitus, otitis media, cataract, altered taste, blepharitis; increased lacrimation, frequent blinking, otitis externa, amblyopia, deafness, diplopia, eye hemorrhage, photophobia, urinary incontinence; cystitis, urinary frequency, leukorrhea, urinary retention, hematuria, dysuria, amenorrhea, abnormal ejaculation, vaginal hemorrhage, vaginal moniliasis, kidney failure, uterus hemorrhage, menorrhagia, albuminuria, kidney calculus, nocturia, polyuria, urinary urgency; breast pain, cervicitis, female lactation, anorgasmy, urinary burning, glycosuria, gynecomastia, urolithiasis, priapism.

MARKETED BY:

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(Additional information is available on request)