

Aripiprazole

Abdin

5 mg / 10 mg Tablet
ANTIPSYCHOTIC

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS AND SUICIDAL THOUGHTS AND BEHAVIORS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Aripiprazole is not approved for the treatment of patients with dementia-related psychosis.

FORMULATION:

Each tablet contains:

Aripiprazole5 mg
Aripiprazole 10 mg

PRODUCT DESCRIPTION:

Aripiprazole (Abdin) 5 mg tablet is a pink, 8.5mm x 5mm, mottled, oval-shaped, biconvex tablet, scored on one side and plain on the other side.

Aripiprazole (Abdin) 10 mg tablet is a pink, 11mm x 6mm, mottled, oval-shaped, biconvex tablet, scored on one side and plain on the other side.

CLINICAL PHARMACOLOGY:

Pharmacodynamics:

Aripiprazole functions as a partial agonist at the dopamine D2 and the serotonin 5-HT1A receptors, and as an antagonist at serotonin 5-HT2A receptor.

Pharmacokinetics:

Aripiprazole is well absorbed from the gastrointestinal tract after oral doses with peak plasma concentrations reached in about 3 to 5 hours. The absolute bioavailability is reported to be 87% with tablet formulations and it is widely distributed. It is metabolized mainly in the liver and pathways involved include dehydrogenation and hydroxylation, via the cytochrome P450 isoenzymes CYP3A4 and CYP2D6, and N-dealkylation, via CYP3A4. The major metabolite, dehydro-aripiprazole, is also active and represents about 40% of the plasma levels of aripiprazole. The mean elimination half-lives of aripiprazole and dehydro-aripiprazole are about 75 and 95 hours, respectively; in a minority of poor metabolizers the half-life of aripiprazole may be extended to about 146 hours.

INDICATION:

It is indicated for the treatment of Schizophrenia.

DOSAGE AND ADMINISTRATION:

Usual Dose for Schizophrenia:

Adults: The recommended starting and target dose for Aripiprazole (Abdin) tablet is 10 mg/day or 15 mg/day orally administered once daily. Therapeutic dose range is 10 mg/day to 30 mg/day; however, doses higher than 10 mg/day or 15 mg/day were not more effective than 10 mg/day or 15 mg/day. Dosage increases should not be made before 2 weeks, the time needed to achieve steady state.

Adolescents: Aripiprazole (Abdin) tablet is indicated for the treatment of Schizophrenia in adolescents 13 to 17 years of age.

CONTRAINDICATIONS:

It is contraindicated in patients with known hypersensitivity reaction to Aripiprazole (Abdin) tablet or any of its ingredients. Reactions may range from pruritus/urticaria to anaphylaxis.

PRECAUTIONS:

Aripiprazole (Abdin) tablet may affect the performance of skilled tasks including driving.

PREGNANCY AND LACTATION:

Pregnancy Category C - Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms.

ADVERSE EFFECTS:

Gastrointestinal disorders: Constipation, dyspepsia, nausea and vomiting
Neurological disorders: Neuroleptic Malignant Syndrome (NMS), headache, anxiety, insomnia, lightheadedness, seizures, and drowsiness
Musculoskeletal disorders: Extrapyramidal effects (common with akathisia), tardive dyskinesia
Metabolism disorder: Weight gain
Cardiovascular system disorders: tachycardia, orthostatic hypotension, bradycardia, ventricular arrhythmias, cardiac arrest, QT prolongation and torsades de pointes.

**"For suspected adverse drug reaction, report to FDA: www.fda.gov/ph.
Seek medical attention immediately at first sign of any adverse drug reaction."**

DRUG INTERACTIONS:

Potential for Other Drugs to Affect Aripiprazole: Aripiprazole is not a substrate of CYP1A1, CYP1A2, CYP2A6, CYP2B6, CYP2B8, CYP2B9, CYP2C19, or CYP2E1 enzymes. Aripiprazole also does not undergo direct glucuronidation. This suggests that an interaction of aripiprazole with inhibitors or inducers of these enzymes, or other factors, like smoking, is unlikely. Both CYP3A4 and CYP2D6 are responsible for aripiprazole metabolism. Agents that induce CYP3A4 (e.g., carbamazepine) could cause an increase in aripiprazole clearance and lower blood levels. Inhibitors of CYP3A4 (ketoconazole) or CYP2D6 (e.g., quinidine, fluoxetine, or paroxetine) can inhibit aripiprazole elimination and cause increased blood levels.

The central effects of other CNS depressants including alcohol may be enhanced by aripiprazole. Aripiprazole may also enhance the effects of antihypertensive drugs. It should be used with caution in patients also receiving drugs that prolong the QT interval or cause electrolyte imbalance. Aripiprazole is metabolized by the cytochrome P450 isoenzymes CYP3A4 and CYP2D6. Ketoconazole, a potent CYP3A4 inhibitor, can increase aripiprazole plasma concentrations by about 60%; licensed product information states that the dose of aripiprazole should be reduced by half when given with ketoconazole. Similarly, the dose of aripiprazole should be halved when given with quinidine, a potent inhibitor of CYP2D6. Conversely, plasma concentration of aripiprazole may decrease by about 70% when given with carbamazepine, a potent CYP3A4 inducer, the dose of aripiprazole should be doubled if carbamazepine is added to aripiprazole treatment. Similar effects may occur with other potent inhibitors or inducers of these isoenzymes and a reduced or increased dose of aripiprazole, respectively in such combinations is recommended.

Antiepileptics: Stevens-Johnson syndrome may occur on use of aripiprazole with lamotrigine.

OVERDOSE AND MANAGEMENT:

Signs and symptoms of overdose may include vomiting, somnolence, tremor, acidosis, aggression, increased aspartate aminotransferase, atrial fibrillation, bradycardia, coma, confusional state, convulsion, increased blood creatine phosphokinase, depressed level of consciousness, hypertension, hypokalemia, hypotension, lethargy, loss of consciousness, prolonged QRS complex, prolonged QT, pneumonia aspiration, respiratory arrest, status epilepticus, and tachycardia.

There is no specific antidote for Aripiprazole (Abdin) tablet overdose. For this reason, supportive measures should immediately be taken until the patient recovers. An electrocardiogram should be obtained in case of overdosage and if QT interval prolongation is present, cardiac monitoring should be instituted. Early administration of activated charcoal may reduce drug absorption of aripiprazole whereas hemodialysis may not be useful since it is highly protein bound.

CAUTION:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:

Store at temperatures not exceeding 30°C.
Keep out of reach of children.

AVAILABILITY:

Aripiprazole (Abdin) 5 mg Tablet.....Alu/PVC White Opaque Blister Pack x 10's (Box of 30 tablets)
Registration No.: DRP-7795
Date of First Authorization: May 2014

Aripiprazole (Abdin) 10 mg Tablet.....Alu/PVC White Opaque Blister Pack x 10's (Box of 30 tablets)
Registration No.: DRP-7796
Date of First Authorization: September 2014

Date of Revision of Package Insert: October 2018

Manufactured for:
MEDCHOICE CNS PHARMA CORPORATION
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Streets, Salcedo Village, Makati City

By:
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