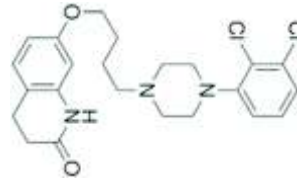


Rx **ARIPIPIRAZOLE**
 (Vial contains 8.8 mg somatropin, 60.2 mg sucrose
 and 2.05 mg O-phosphoric acid)



Aripiprazole is an anti-psychotic drug for treating psychoses. Like other anti-psychotic drugs, the mechanism of action of aripiprazole is unknown. Moreover, like other anti-psychotics, it blocks several receptors on the nerves of the brain for several neurotransmitters (chemicals that nerves use to communicate with each other). *It is thought that its beneficial effect is due to its effects on dopamine and serotonin receptors. Its effects on these receptors are complex, involving stimulation of the receptors but to a lesser degree than the naturally-occurring neurotransmitters (a process called partial agonism).*
The FDA approved aripiprazole in November 2002.

PRESCRIPTION: Yes.

GENERIC AVAILABLE: No.

PREPARATIONS: Tablets: 10, 15, 20, and 30 mg. Oral solution: 1 mg/mL

STORAGE: Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

PRESCRIBED FOR: Aripiprazole is used to treat schizophrenia, bipolar mania and mixed manic/depressive episodes (as sole or adjunctive therapy) and as adjunctive (add-on) therapy for major depressive disorder.

DOSING: Aripiprazole usually is taken once a day. The usual starting dose is 10 or 15 mg once daily. The dose may be increased over time to achieve the desired effect. Aripiprazole can be taken with or without food.

DRUG INTERACTIONS: Carbamazepine (Tegretol) can markedly decrease the amount of aripiprazole in the body by increasing the rate at which the body's enzymes (particularly the liver enzyme, CYP3A4) degrade it. The manufacturer recommends that patients on aripiprazole who are started on carbamazepine double their dose of aripiprazole, under their doctor's supervision. Other drugs that can promote the activity of CYP3A4 and decrease the body's levels of aripiprazole are phenytoin (Dilantin), rifampin (Rifadin, Rimactane, Rifadin, Rifater, Rifamate), and phenobarbital.

Ketoconazole (Nizoral) can increase the amount of aripiprazole in the body by blocking **CYP3A4**. The manufacturer of aripiprazole recommends reducing the dose of aripiprazole by one-half during ketoconazole therapy. Many other drugs also are known to block CYP3A4 and potentially could increase the levels of aripiprazole, but their actual effects on aripiprazole levels have not been studied. Such drugs include: itraconazole (Sporanox), fluconazole (Diflucan), voriconazole (Vfend), cimetidine (Tagamet), verapamil (Calan, Isoptin), diltiazem (Cardizem, Dilacor), erythromycin, clarithromycin (Biaxin), nefazodone (Serzone), ritonavir (Norvir), saquinavir (Invirase), nelfinavir (Viracept), indinavir (Crixivan), and grapefruit juice.

Quinidine (**Quinaglute, Quinidex**) inhibits another liver enzyme known as **CYP2D6** that also breaks down aripiprazole and can increase the amount of aripiprazole in the body. The manufacturer of aripiprazole recommends *reducing the dose of aripiprazole by one-half during quinidine therapy.* Other medicines that block CYP2D6 include fluoxetine (Prozac) and paroxetine (Paxil).

USES: This medication is used to treat schizophrenia. **It works by helping to restore the balance of certain natural chemicals in the brain** (neurotransmitters).

Aripiprazole HOW TO USE: Take this medication by mouth, usually once daily, with or without food; or take as directed by your doctor. Do not take this medication more often or increase your dose without consulting your doctor. Your condition will not improve any faster but the risk of serious side effects will be increased. Do not stop taking this drug without your doctor's approval. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time each day.

SIDE EFFECTS: Vomiting, fever, lightheadedness, dizziness change in weight, blurred vision or drowsiness may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: irregular or unusually fast heartbeat (especially with fever and increased sweating), severe muscle stiffness, uncontrolled muscle movements (especially of the face or tongue), unusual increase in thirst or urination, vision changes. **A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing.** If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS: Before taking aripiprazole, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: heart disease (e.g., history of heart attacks or chest pain, heart failure, irregular heart rhythm), history of stroke, dehydration, seizures, Alzheimer's disease, swallowing problems (e.g., history of aspiration), diabetes (or family history), obesity. To minimize dizziness or fainting, get up slowly from a lying or seated position (especially when you first start using this drug or if your doctor changes your dose). This medication can reduce sweating, which makes overheating more likely to occur. Avoid activities that might cause you to overheat (e.g., doing strenuous work, exercising in hot weather, or using hot tubs). Drink plenty of fluids to avoid becoming dehydrated. This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Avoid alcoholic beverages. Caution is advised when using this drug in the elderly because they may be more sensitive to its side effects. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug passes into breast milk. Breast-feeding is not recommended while using this drug.

WARNINGS: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS and SUICIDALITY AND ANTIDEPRESSANT DRUGS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (**modal duration of 10 weeks**), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between **1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%**, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (eg, heart failure, sudden death) or infectious (eg, pneumonia) in nature. *Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality.* The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. Aripiprazole is not approved for the treatment of patients with dementia-



Taj Group of Companies ^{INDIA}

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91,
 (0)22 - 26374592/93 91 - (0)22 - 30601000,
 Fax : 91-(0)22-26341274

Revised November 2010