APIZOLE 5
Aripiprazole Tablets USP 5mg

Consumer Medicine Information
What is in this leaflet?
This leaflet contains answers to some common questions about Aripiprazole. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risk of you using this medicine against the benefits he/she expects it will have for you.
If you have any concerns about using this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What does Aripiprazole look like? (Dosage Form)
White colour round shape biconvex uncoated tablet with one side breakline and other side plain.

Is this oral or injectable? (Route of Administration)
It is to be consumed orally, swallowed with water. Do not chew the tablet.

Ingredients / Content / Volume:
Each uncoated tablet contains:
Aripiprazole USP…. 5 mg
Excipients …..……...Q.S.

How to store Aripiprazole? (Storage temperature & conditions)
Store in a cool and dry place at temperature below 30°C. Keep medicine away from children.

What other ingredients are in this medicine beside the active one? (Declaration of Excipients)
Lactose BP, Starch BP, M.C.C.P. (Flocel – 101) JRS BP, P.V.P.K. 30 USP, Iso Propyl Alcohol BP, Magnesium Stearate BP, Talcum BP, Croscarmellose Sodium BP, Sodium Starch Glycolate Type A (Potato Based) BP, Fumed Silica IH.

Do I need a prescription to get this medicine? (Dispensing Condition)
Yes, Prescription Medication Only.

What age group is this medicine suitable for? (Age Indication)
Children: 6 years and above.
Adults: 18 years and above.

What Aripiprazole is used for? (Indications)
Aripiprazole is a typical antipsychotic drug, indicated for treatment of Autism, schizophrenia, for acute maniac and mixed episodes associated with bipolar I disorder, and Tourette's disorder. It is also used as an adjunctive treatment of major depressive disorder.

How should I take this medicine? (Method of Use)
It is to be consumed orally, swallowed with water. Do not chew the tablet.

What is the dosage schedule and dose duration?
Initial dose is 5 mg and maximum dose is 30 mg.
a) For Bipolar Mania:
Adults: At first 15 mg once a day.
When it is given with lithium or valproate, the starting dose is 10 to 15 mg once a day. Your doctor may adjust your dose as needed. However, the dose is usually not more than 30 mg per day.

Children 13 years of age and older: At first, 2 mg once a day. The dose will be gradually increased to 10 mg once a day. The doctor may adjust your dose again as needed. However, the dose is usually
not more than 30 mg per day.

b) For Depression:
Adults: At first, 2 to 5 milligrams (mg) once a day. Your doctor may adjust your dose as needed. However, the dose is usually not more than 15 mg per day.

c) For irritability in children with autistic disorder:
Children 6 to 17 years of age: At first, 2 milligrams (mg) once a day. Your doctor may adjust your dose as needed. However, the dose is usually not more than 15 mg per day.
Children younger than 6 years of age: Use and dose

must be determined by your doctor.

d) For schizophrenia:

Adults: At first, 10 to 15 milligrams (mg) once a day. Your doctor may adjust your dose as needed. However, the dose is usually not more than 30 mg per day.

Children 15 years and older: At first, 2 mg once a day. The dose will be gradually increased to 10 mg once a day. Your doctor may adjust your dose again as needed. However, the dose is usually not more than 30 mg per day.

Children younger than 15 years of age: Use and dose must be determined by your doctor.

e) For Tourette's disorder:

Children 6 to 18 years of age: At first, 2 milligrams (mg) once a day. Your doctor may adjust your dose as needed. However, the dose is usually not more than 20 mg per day.

Children younger than 6 years of age: Use and dose must be determined by your doctor.

What are the signs of an Overdose: Common adverse reactions (reported in at least 5% of all overdose cases) reported with oral aripiprazole overdosage (alone or in combination with other substances) include vomiting, somnolence, and tremor.

What should I do immediately if someone has Overdosed? (Overdose Management): No specific information is available on the treatment of overdose with Aripiprazole. If over-exposure occurs call your doctor immediately. An electrocardiogram should be obtained in case of overdosage and if QT interval prolongation is present, cardiac monitoring should be instituted. Otherwise, management of overdose should concentrate on supportive therapy, maintaining an adequate airway, oxygenation and ventilation, and management of symptoms. Close medical supervision and monitoring should continue until the patient recovers.

Charcoal: In the event of an overdose of Aripiprazole, an early charcoal administration may be useful in partially preventing the absorption of aripiprazole.

Warning & Precaution: Is there anything I should be careful about while taking this medicine?

Before treatment with Aripiprazole, tell your doctor if you suffer from:

• High blood sugar (characterised by symptoms such as excessive thirst, passing of large amounts of urine, increase in appetite, and feeling weak) or family history of diabetes.

• Fits (seizures) since your doctor may want to monitor you more closely.

• Involuntary, irregular muscle movements, especially in the face.

• Cardiovascular diseases, family history of cardiovascular disease, stroke or "mini" stroke, abnormal blood pressure

• Blood clots, or family history of blood clots.

Consult your doctor immediately: if you notice you are gaining weight, develop unusual movements, experience somnolence that interferes with normal daily activities, any difficulty in swallowing or allergic symptoms, having any thoughts or feelings about hurting yourself, muscle stiffness, inflexibility with high fever, altered mental status, or very rapid or irregular heartbeat, impulsive control disorders like addictive gambling, excessive eating or spending, abnormally high sex drive.

If you are an elderly patient suffering from dementia (loss of memory and other mental abilities), you or your carer/relative should tell your doctor if you have ever had a stroke or "mini" stroke.

Who should not take this medicine? (Contraindications)

If allergic or hypersensitivity to Aripiprazole, and lactose intolerant patients.

Does this medicine interact with any other drugs I'm taking? Drug Interactions:
Drug interactions may change how your medications work or increase your risk for serious side effects. Keep a list of all the products you use (including prescription/non-prescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Is it safe during pregnancy or breast feeding?
Consult your doctor if you are pregnant, or planning to have a baby or during breast feeding, before consuming Aripiprazole. There is no good evidence that taking aripiprazole in early pregnancy will affect your baby.

Is it safe to drive or operate machine using this medicine?
Dizziness and vision problems may occur during treatment with this medicine. This should be considered in cases where full alertness is required, e.g. when driving a car or handling machines.

If I am Lactose Intolerant?
Inform your doctor if you are lactose intolerant as Aripiprazole contains lactose monohydrate.

How does this medicine work? (Pharmacological Information)
Aripiprazole is an antipsychotic medication that helps treat several kinds of mental health conditions, including schizophrenia, bipolar I disorder, autism spectrum disorder and Tourette syndrome. It balances the levels of dopamine and serotonin in your brain to regulate your mood, behaviours and thoughts.

What Side Effects can this medicine cause?
Common Side effects may include dizziness, light headedness (this may increase the risk of falling, get up slowly when rising from a sitting or lying position), Nausea and Vomiting, tiredness, excessive saliva (drooling), blurred vision, trouble sleeping, mood swings, irritability, weight gain & constipation.

How does the packaging of this medicine look like?
There are 10 tablets in one strip and 3 such strips in a box with leaflet.

Manufacturer & Product License Holder:
Rhombus Pharma Pvt Ltd.
Survey No 807/002, Near Ethrico Industries, Lakshmanpura, Ta: Kadi, Dist: Mehsana 382165. Gujarat. India

Marketing Authorisation Holder:
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