Aripiprazole Accord 5, 10, 15 and 30 mg tablets

EDUCATIONAL MATERIAL FOR THE PATIENTS AND THEIR CAREGIVERS

Introduction

Your doctor has diagnosed you with bipolar I disorder and prescribed Aripiprazole. This booklet will help you and your caregiver(s) understand what Aripiprazole is and why it was chosen for you, as well as what to expect during treatment. This booklet also includes information about potential side effects associated with Aripiprazole treatment and the importance of immediately reporting any symptoms of these side effects to your doctor.

What is Bipolar I Disorder?

Bipolar disorder (formerly called manic-depression) in adolescents is characterised by the occurrence of one or more manic or mixed (manic- depressive) episodes. This may involve experiencing symptoms such as feeling 'high', having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas, and sometimes severe irritability.

Bipolar I disorder can significantly impact your wellbeing, and treatment is necessary to make sure it does not negatively impact your relationships with friends and family or your success at school.

What is Aripiprazole Treatment?

Aripiprazole is a drug that has been developed for the treatment up to 12 weeks of moderate-to-severe manic episodes in adolescents with bipolar I disorder aged 13–17 years old. Aripiprazole is not recommended for use in patients below 13 years old.

While the exact mechanism of action of Aripiprazole is not currently known, Aripiprazole is capable of reducing manic symptoms in patients with bipolar I disorder. It is thought that Aripiprazole achieves this by normalizing overactive signalling pathways in the brain of patients with bipolar I disorder. Signals within the brain are mediated by molecules called 'neurotransmitters' and Aripiprazole is known to limit the activity of two neurotransmitters called dopamine and serotonin, and this action is believed to be responsible for the therapeutic effect of Aripiprazole.

What Should I Expect From My Treatment?

Before Treatment

Before taking Aripiprazole, your doctor will need to make sure that this medication is suitable for you. In particular, your doctor needs to check that you are not hypersensitive (allergic) to Aripiprazole or any of the other ingredients used when preparing Aripiprazole.

In addition, before beginning treatment with Aripiprazole, please ensure that you tell your doctor about all the medications you are taking, and in particular, if you suffer from any of the following:

- High blood sugar/diabetes (characterised by symptoms such as excessive thirst, passing of large amounts of urine, increase in appetite, and feeling weak), or family history of diabetes
- Seizures
- Involuntary, irregular muscle movements, especially in the face
- Cardiovascular diseases, stroke or 'mini' stroke, abnormal blood pressure or have a family history of cardiovascular disease e.g. myocardial infarction (heart attack) or coronary artery disease
- Blood clots, or family history of blood clots, as antipsychotics have been associated with formation of blood clots
- Attention-deficit hyperactivity disorder (ADHD): despite the high comorbidity frequency of bipolar I disorder and ADHD, very limited safety data are available on concomitant use of Aripiprazole and stimulants (e.g. methylphenidate); therefore, extreme caution should be taken when these drugs are co-administered.

This is important to minimise the risk of side effects while you are being treated with Aripiprazole.

Administration: How Do I Take Aripiprazole?

The standard dose of Aripiprazole is 10 mg once daily. However, you will not start on a 10 mg dose immediately. The following schedule will allow your body to be gradually introduced to Aripiprazole when you begin treatment:

- On Days 1 and 2, you will take 2 mL of a liquid containing aripiprazole at a concentration of 1 mg/mL each day (total dose = 2 mg aripiprazole).
- On Days 3 and 4, you will take 5 mg Aripiprazole each day
- From Day 5 onwards you will take 10 mg Aripiprazole at the same time each day

Enhanced efficacy at doses higher than a daily dose of 10 mg has not been demonstrated, and a daily dose of 30 mg is associated with a substantially higher incidence of significant undesirable effects including extrapyramidal- symptom-related events, somnolence, fatigue and weight gain in adolescent patients with bipolar I disorder. Doses higher than 10 mg/day should therefore only be used in exceptional cases and with close clinical monitoring.

Try to take the Aripiprazole tablet at the same time each day.

It does not matter whether you take it with or without food. Always take the tablet with water and swallow it whole, and if you miss a dose, take the missed dose as soon as you remember, but do not take two doses in 1 day.

Even if you feel better, do not alter or discontinue your daily dose of Aripiprazole without first consulting your doctor.

You should always take Aripiprazole exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How Long Will Aripiprazole Take to Work?

The time it takes to start feeling better is different from person to person. Your doctor will explain what to expect from your treatment with Aripiprazole.

You should always take Aripiprazole exactly as your doctor has told you. If you have the impression that the effect of Aripiprazole is too strong or too weak, talk to your doctor or pharmacist. Even if you feel better, do not alter or discontinue the daily dose of Aripiprazole without first consulting your doctor.

How Long Do I Need to Take Aripiprazole For?

You will need to keep taking Aripiprazole at least until your symptoms are adequately controlled. However, Aripiprazole treatment is only recommended for up to 12 weeks.

Please remember that you should always take Aripiprazole exactly as your doctor has told you, and you should check with your doctor or pharmacist if you are not sure.

What Possible Side Effects Could I Experience?

Aripiprazole can cause side effects; although, not everybody gets them.

If you experience any of the side effects listed in the Aripiprazole package leaflet and they become serious, or if you notice any side effects not listed in the leaflet, you should tell your doctor or pharmacist. In particular, if you notice that you are gaining weight, have developed unusual movements, experience fatigue, sleepiness or tiredness that interferes with normal daily activities or have any difficulty in swallowing or allergic symptoms, you should inform your doctor.

You should also tell your doctor immediately if you are having any thoughts or feelings about hurting yourself, as suicidal thoughts and behaviours have been reported by patients being treated with Aripiprazole. Likewise, you should inform your doctor immediately if you suffer from muscle stiffness or inflexibility with high fever, sweating, altered mental status or a very rapid or irregular heartbeat.

The Main Side Effects of Your Treatment

Important potential side effects in adolescent patients with bipolar I disorder treated with Aripiprazole	Signs or symptoms
Weight gain	Weight gain in excess of that expected due to normal growth Increased appetite
Extrapyramidal symptoms	Uncontrollable twitching or jerking movements Muscle twitching Uncontrolled movements of the limbs Restlessness
Fatigue	Tiredness
Somnolence	Sleepiness Drowsiness
Neuroleptic malignant syndrome	High fever Stiff muscles Confusion Sweating Changes in pulse, heart rate and blood pressure
Hyperglycaemia (high blood sugar)	Increases in thirst, urination or hunger Feeling weak, tired or confused Feeling sick to your stomach Fruity smelling breath
Tardive dyskinesia	Uncontrollable movements of your face, tongue or other parts of the body
Orthostatic hypotension	Light-headedness Fainting when rising too quickly from a sitting or lying position
Hypersensitivity	Symptoms of an allergic reaction e.g. skin rashes, particularly hives, itching, breathing problems or swelling in the face

Adolescent patients with bipolar I disorder aged between 13 and 17 years old treated with Aripiprazole generally experience side effects that are comparable with those seen in adults. Side effects not listed above that are considered to be common in adults, in that they are observed in 1–10 out of every 100 patients, include headache, nausea, vomiting, an uncomfortable feeling in the stomach, constipation, increased production of saliva, trouble sleeping, feeling anxious, shaking and blurred vision. Some patients may also feel depressed.

However, some side effects were more common in clinical trials in adolescent patients with bipolar I disorder treated with Aripiprazole. Upper abdominal pain, dry mouth, increased heart rate and feeling dizzy, especially when getting up from a lying or sitting position, were common (greater than one in 100 patients). If you experience any of these side effects, you should inform your doctor.

Remember that everyone reacts differently to medication, and your body may still need time to adjust. So before making any changes to your routine, or stopping medication, be sure to talk to your doctor.

Monitoring Your Symptoms of Potential Side Effects

Why is it Important to Watch for Symptoms of the Side Effects of Aripiprazole?

It is important that any side effects associated with your treatment be recognised early as this will enable your doctor to address them promptly and prevent the symptoms of these side effects from becoming worse. If the side effects are significant, your doctor should consider adjusting the dose of Aripiprazole or may stop treatment especially if you experience the following side effects:-

- Hypersensitivity (skin rashes, particularly hives, itching, breathing problems or swelling of the face
- Neuroleptic Malignant Syndrome (high fever, stiff muscles, confusion, sweating, changes in pulse, heart rate and blood pressure)
- Suicidal thoughts and behaviours.

What are the Side Effects That I Need to Look Out For?

- **Weight gain:**

  Weight gain has been reported among patients prescribed Aripiprazole. In a clinical trial, adolescent patients treated with Aripiprazole over 12 weeks had weight gain of 2.4 kg compared with 0.2 kg in patients given a placebo.

  As part of your treatment plan, your doctor should monitor your weight and compare any weight gain against that expected with normal growth.

- **Extrapyramidal symptoms:**

  Extrapyramidal symptoms are characterised by muscle stiffness, involuntary movements, shakes, ticks etc., and were observed in 9.1% of adolescent patients with bipolar I disorder administered Aripiprazole 10 mg in clinical trials.

  The risk of adolescent patients with bipolar I disorder experiencing extrapyramidal symptoms increases with higher doses of Aripiprazole, so please remember to always take Aripiprazole exactly as your doctor has told you.

- **Fatigue:**

  More than 1 in 10 adolescent patients (11.8%) enrolled in a clinical trial examining the use of Aripiprazole to treat bipolar I disorder exhibited signs of fatigue or tiredness during treatment. Because of this, it is recommended that you do not drive or use any tools or machines until you know how Aripiprazole affects you.

- **Somnolence:**

  Somnolence means drowsiness or sleepiness, and was observed in more than 1 in 10 adolescent patients (23.0%) with bipolar I disorder treated with Aripiprazole in clinical trials. Because of this, it is recommended that you do not drive or use any tools or machines until you know how Aripiprazole affects you.

Reminder: What Do I Do if I Experience Any Side Effects?

Remember that everyone reacts differently to medication, and your body may still need time to adjust. So before making any changes to your routine, or stopping medication, be sure to talk to your doctor.

Likewise, if you experience any of the side effects listed in the Aripiprazole package leaflet and they become serious, or if you notice any side effects not listed in the leaflet, you should not attempt to self-treat them, and should tell your doctor or pharmacist.

In particular, if you notice that you are gaining weight, have developed unusual movements, experience fatigue, sleepiness, or tiredness that interferes with normal daily activities, experience suicidal thoughts, or signs of Neuroleptic Malignant Syndrome (high fever, stiff muscles, confusion, sweating, changes in pulse, heart rate and blood pressure) or have any difficulty in swallowing or allergic symptoms, you should tell your doctor.

• Adverse events should be reported via national reporting system.

• The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GZR-1368 Gzira,
www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt
or
www.medicinesauthority.gov.mt/adrportal

• Adverse events should also be reported to ACCORD on +44 -0208 901 3370 or safety@lambda-cro.com

Notes

Aripiprazole Accord

Where Can I Obtain More Information?

- Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/
- Adverse events should be reported via national reporting system.
- The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GZR-1368 Gzira,
  www.medicinesauthority.gov.mt
  e-mail: postlicensing.medicinesauthority@gov.mt
  or
  www.medicinesauthority.gov.mt/adrportal
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