

Your guide to ABILIFY[®] (aripiprazole)
Oral Formulations

**Patient/Caregiver Information Brochure
For Bipolar I Disorder in Adolescents**



Bristol-Myers Squibb



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Introduction

Your doctor has diagnosed you with bipolar I disorder and prescribed ABILIFY (aripiprazole) in oral form (tablets or liquid). This booklet will help you and your caregiver(s) understand what ABILIFY (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 ABILIFY (aripiprazole) treatment and the importance of immediately reporting any symptoms of these side effects to your doctor.

What is Bipolar I Disorder?

Bipolar I 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 ABILIFY (aripiprazole) Treatment?

ABILIFY (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. ABILIFY (aripiprazole) is not recommended for use in patients below 13 years old.

While the exact mechanism of action of ABILIFY (aripiprazole) is not currently known, ABILIFY (aripiprazole) is capable of reducing manic symptoms in patients with bipolar I disorder. It is thought that ABILIFY (aripiprazole) achieves this by normalising overactive signalling pathways in the brain of patients with bipolar I disorder. Signals within the brain are mediated by molecules called 'neurotransmitters' and ABILIFY (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 ABILIFY (aripiprazole).

What Should I Expect From My Treatment?

Before Treatment

Before taking ABILIFY® (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 ABILIFY® (aripiprazole) or any of the other ingredients used when preparing ABILIFY® (aripiprazole).

In addition, before beginning treatment with ABILIFY® (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): and are taking medication to manage it as very little is known about the safety of taking aripiprazole at the same time as stimulants that may be used to manage ADHD

This is important to minimise the risk of side effects while you are being treated with ABILIFY® (aripiprazole).

Administration: How Do I Take ABILIFY® (aripiprazole)?

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

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

The standard dose of ABILIFY® (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 ABILIFY® (aripiprazole) when you begin treatment:

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

Your doctor may prescribe a lower or higher dose to a maximum of 30mg once a day. Doses higher than a daily dose of 10mg have not been shown to provide extra efficacy in clinical trials.

Patients taking a daily dose of 30mg have a much higher risk of experiencing side effects, in particular muscle stiffness, involuntary movements, shakes, ticks, restlessness etc. (extrapyramidal side effects), feeling tired, sleepy or drowsy (fatigue and somnolence) and weight gain. If you experience any side effects with your current dose of aripiprazole, it is important to inform your doctor or pharmacist as soon as possible if they become serious or if they are not listed in the ABILIFY® (aripiprazole) package leaflet.

Try to take the ABILIFY® (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. If you miss a dose, take the missed dose as soon as you remember, but do not take two doses in 1 day.

How Long Will ABILIFY® (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 ABILIFY® (aripiprazole).

You should always take ABILIFY® (aripiprazole) exactly as your doctor has told you. If you have the impression that the effect of ABILIFY® (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 ABILIFY® (aripiprazole) without first consulting your doctor.

How Long Do I Need to Take ABILIFY® (aripiprazole) For?

You will need to keep taking ABILIFY® (aripiprazole) at least until your doctor is satisfied your symptoms are adequately controlled. However, ABILIFY® (aripiprazole) treatment is only recommended for up to 12 weeks.

Please remember that you should always take ABILIFY® (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?

ABILIFY® (aripiprazole) can cause side effects; although, not everybody gets them.

If you experience any of the side effects listed in the ABILIFY® (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 (e.g. swelling in the mouth, tongue, face and throat, itching, rash) 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 ABILIFY® (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 ABILIFY® (aripiprazole)

Signs or symptoms

Weight gain	<ul style="list-style-type: none"> • Weight gain in excess of that expected due to normal growth • Increased appetite
Extrapyramidal symptoms	<ul style="list-style-type: none"> • Uncontrollable or involuntary twitching or jerking movements • Muscle twitching, shakes, ticks • Muscle stiffness • Uncontrolled movements of the limbs • Restlessness
Fatigue	<ul style="list-style-type: none"> • Tiredness
Somnolence	<ul style="list-style-type: none"> • Sleepiness • Drowsiness
Neuroleptic malignant syndrome	<ul style="list-style-type: none"> • High fever • Stiff muscles • Confusion • Sweating • Changes in pulse, heart rate and blood pressure
Hyperglycaemia (high blood sugar)	<ul style="list-style-type: none"> • Increases in thirst, urination or hunger • Feeling weak, tired or confused • Feeling sick to your stomach • Fruity smelling breath
Tardive dyskinesia	<ul style="list-style-type: none"> • Uncontrollable movements of your face, tongue or other parts of the body
Orthostatic hypotension	<ul style="list-style-type: none"> • Light-headedness • Fainting when rising too quickly from a sitting or lying position
Hypersensitivity	<ul style="list-style-type: none"> • Symptoms of an allergic reaction e.g. skin rashes, particularly hives, itching, breathing problems or swelling in the face

Like all medicines, ABILIFY® can cause side effects, although not everybody gets them and they do not always persist long term.

Adolescent patients with bipolar I disorder aged between 13 and 17 years old treated with ABILIFY® (aripiprazole) generally experience side effects that are comparable with those seen in adults. Side effects not listed in the table on the previous page, 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 ABILIFY® (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 ABILIFY® (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 ABILIFY® (aripiprazole).

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

- **Weight gain:**

Weight gain has been reported among patients prescribed ABILIFY® (aripiprazole).

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, restlessness, etc., and were seen in just under one in 10 adolescent patients with bipolar I disorder administered ABILIFY® (aripiprazole) 10 mg in clinical trials.

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

- **Fatigue and somnolence**

Just over one in ten adolescent patients taking ABILIFY® (aripiprazole) for Bipolar I disorder in clinical trials experienced fatigue or tiredness. Drowsiness or sleepiness (somnolence) were very common (approximately 1 in 5 patients).

Because of this, it is recommended that you do not drive or use any hazardous tools or machines until you know how ABILIFY® (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 your medication, be sure to talk to your doctor.

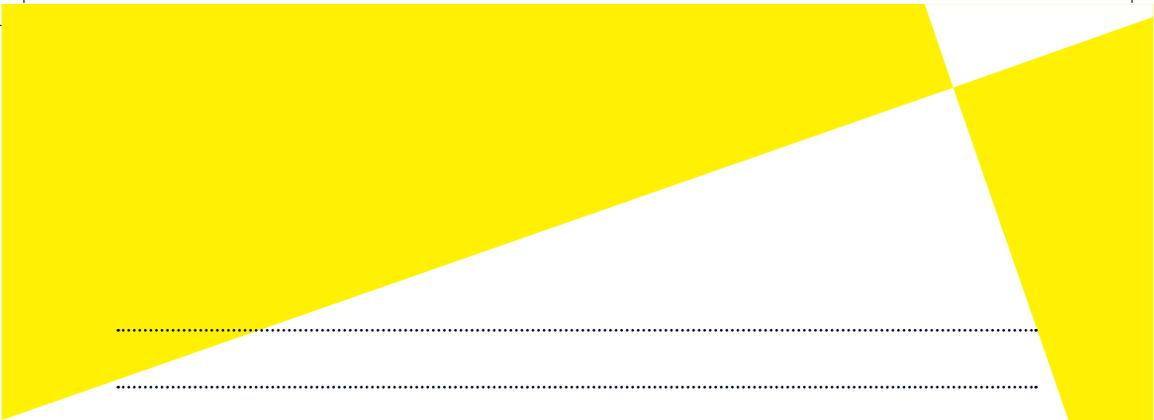
Likewise, if you experience any of the side effects listed in the ABILIFY® (aripiprazole) package leaflet and they become serious, or if you notice any side effects not listed in the leaflet, you should not attempt to self-treat them, and should tell your doctor or pharmacist.

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 or have any difficulty in swallowing or allergic symptoms, you should tell your doctor.

You are also encouraged to report any side effects to the Irish Medicines Board (IMB). Reporting forms and information can be found at www.imb.ie. Side effects can also be reported to the Irish Medicines Board by calling on (01) 6764971. Side effects may also be reported to Bristol-Myers Squibb Pharmaceuticals Medical Information on 1800 749 749 or medical.information@bms.com.

Notes

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Where to find further information:

Please consult the Patient Information Leaflet (PIL) in the ABILIFY® (aripiprazole) product package. The PIL is also available for electronic download at www.medicines.ie.