

## **SCHEDULING STATUS**

S5

## **PROPRIETARY NAME STRENGTH AND PHARMACEUTICAL FORM**

**ABILIFY** 5, 10 or 15 mg tablets

### **Read all of this leaflet carefully before you start taking ABILIFY**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- ABILIFY has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

## **WHAT ABILIFY CONTAINS**

**Active ingredient:** Each tablet contains aripiprazole 5, 10 or 15 mg

### **Inactive ingredients:**

Colourants (iron oxide in the 10 and 15 mg tablets and indigo carmine in the 5 mg tablets), hydroxypropylcellulose, lactose, magnesium stearate, microcrystalline cellulose and starch.

## **WHAT ABILIFY IS USED FOR**

### **Schizophrenia:**

ABILIFY is indicated for the treatment of schizophrenia and for the maintenance of clinical improvement in adults.

ABILIFY is one of a group of medicines called antipsychotics. It is used to treat adults suffering from a disease characterized by symptoms such as hearing, seeing or sensing things which are not there, suspiciousness, mistaken beliefs, incoherent speech and behaviour and emotional flatness. People with this condition may also feel depressed, guilty, anxious or tense.

## **Bipolar Mania:**

ABILIFY is indicated for the treatment of acute manic episodes associated with Bipolar I Disorder and for prevention of recurrence of new manic episodes in patients who experienced predominantly manic episodes and who responded to ABILIFY treatment.

ABILIFY is used to treat adults who suffer from a condition with 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.

### **BEFORE YOU TAKE ABILIFY:**

Do not take ABILIFY:

- if you are allergic to aripiprazole or any of the other ingredients in ABILIFY

### **Take special care with ABILIFY:**

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

- High blood sugar or family history of diabetes
- Seizure
- Muscle stiffness or inflexibility with high fever, sweating, altered mental status, or very rapid or irregular heart beat
- Involuntary, irregular muscle movement, especially in the face.
- Cardiovascular disease, family history of cardiovascular disease, stroke or “mini” stroke, abnormal blood pressure.

### **Tell your health care provider if you:**

- Notice you are gaining weight, develop unusual movements, experience sleepiness that interferes with normal daily activities, any difficulty in swallowing or allergic symptoms.
- If you are an elderly patient suffering from dementia (loss of memory and other mental abilities), you or your caregiver/relative should tell your doctor if you have ever had a stroke or “mini” stroke.
- Suicidal thoughts and behaviour have been reported during ABILIFY treatment. Tell your doctor immediately if you are having any thoughts or feelings about hurting yourself.

- Past experience with excessive gambling or other impulsive behaviours

**Children and adolescents.**

ABILIFY is not for use in children and adolescents as it has not been studied in patients under 18 years. Ask your doctor or pharmacist for advice before taking ABILIFY.

**Taking ABILIFY with food and drink:**

ABILIFY can be administered regardless of meals.

Alcohol should be avoided when taking ABILIFY.

**Pregnancy and Breast-feeding**

You should not use ABILIFY if you are pregnant or breast feeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine

The following symptoms may occur in newborn babies, of mothers that have used ABILIFY in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

**Be sure to tell your doctor immediately if you are breastfeeding.**

**If you are taking ABILIFY, you should not breastfeed.**

**Driving and using machines:**

Do not drive or use tools or machines if you feel drowsy after receiving ABILIFY.

**Important information about some of the ingredients of Abilify:**

ABILIFY contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ABILIFY.

### **Taking other medicines with ABILIFY :**

Always tell your health care professional provider if you are taking any other medicine. This includes complementary or traditional medicines.

Blood pressure-lowering medicine: ABILIFY may increase the effect of medicines used to lower the blood pressure. Be sure to tell your doctor if you take a medicine to keep your blood pressure under control.

Taking ABILIFY with some medicines may need to change your dose of ABILIFY. It is especially important to mention the following to your doctor:

- Medicines to correct heart rhythm
- Antidepressants or herbal remedy used to treat depression and anxiety
- Antifungal agents
- Certain medicines to treat HIV infection
- Anticonvulsants used to treat epilepsy.

### **HOW TO TAKE ABILIFY**

#### **ABILIFY tablets:**

Do not share medicines prescribed for you with any other person

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

#### **For Schizophrenia:**

ABILIFY can be started at a dose of 10 or 15 mg/day and thereafter the usual dose is 15 mg once a day. However your doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day.

#### **For Bipolar Mania:**

ABILIFY is started at a dose of 15 mg/day, once a day. The dose can be adjusted at intervals of not less than 24 hours. Your doctor will prescribe the dose recommended for you up to a maximum of 30 mg once per day.

If you have the impression that the effect of ABILIFY is too strong or too weak, talk to your doctor or pharmacist.

**Try to take the ABILIFY 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.

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

#### **If you take more ABILIFY than you should**

If you realise you have taken more ABILIFY tablets than your doctor has recommended (or if someone else has taken some of your ABILIFY tablets), contact your doctor right away. If you cannot reach your doctor, go to the nearest hospital and take the pack with you.

#### **If you forget to take ABILIFY**

If you miss a dose, take the missed dose as soon as you remember but do not take two doses in one day.

**If you have any further questions on the use of this product, ask your doctor or pharmacist.**

Do not share medicines prescribed for you with others. In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

#### **POSSIBLE SIDE-EFFECTS**

ABILIFY can have side-effects.

Not all side effects reported for Abilify are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

**ABILIFY Tablets:**

**Schizophrenia:**

**Very common side-effects** (greater than 1 in 10 patients)

Insomnia (difficulty sleeping), headache.

**Common side-effects** (greater than 1 in 100, less than 1 in 10 patients)

Restlessness, dizziness, inability to sit or lie still, sedation, shaking, movement disorder, blurred vision, fast heart rate, feeling dizzy when getting up from a lying or sitting position, nausea, vomiting, constipation, dyspepsia (uncomfortable feeling in the stomach), fatigue .

**Bipolar Mania:**

**Very common side-effects** (greater than 1 in 10 patients)

Headache, inability to sit or lie still, nausea.

**Common side-effects** (greater than 1 in 100, less than 1 in 10 patients)

Restlessness, feeling anxious, sedation, shaking, movement disorder, sleepiness, blurred vision, constipation, vomiting, increase in salivary secretions, dyspepsia (uncomfortable feeling in the stomach), abdominal discomfort, stomach discomfort, tiredness, muscle stiffness.

**Uncommon side-effects** (greater than 1 in 1 000, less than 1 in 100 patients)

Swelling of hands and feet, fast heart rate, feeling dizzy when getting up from a lying or sitting position.

**If the condition continues or gets worse, contact your doctor as soon as possible.**

**Other findings**

Combination of fever, muscle stiffness, faster breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate, seizures and prolonged muscle contractions (of the neck muscles, tightness of the throat, difficulty swallowing, breathing difficulties and protrusion (bulging of the tongue)). If this happens while you are taking ABILIFY, **contact your doctor immediately.**

### **Post-Introduction Treatment Emergent Adverse Drug Reactions**

Changes in the levels of some blood cells; high blood sugar, onset or worsening of diabetes, ketoacidosis (ketones in the blood and urine) or coma; agitation; excessive gambling, increased sexual interest, impulsive behavior; speech disorder; seizures; double vision; fainting, high blood pressure; inflammation of the pancreas, difficulty in swallowing, diarrhoea; feeling cold, high temperature, chest pain; allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching, rash), excessive sweating, unusual hair loss or thinning; reports of abnormal liver test values, weight gain, weight loss; muscle pain, muscle stiffness; prolonged and or painful erection; involuntary loss of urine, difficulty in passing urine; accidental inhalation of food with risk of pneumonia, hiccups; inflammation of the liver, yellowing of the skin and the white of the eyes; low sodium level in the blood, decreased appetite; thoughts of suicide, suicide attempt and suicide.

**If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.**

### **STORING AND DISPOSING OF ABILIFY**

Store ABILIFY tablets below 30 °C in the original container.

Store all medicines out of reach of children.

Return unused medicine to the pharmacy.

Do not use after the expiry date stated on the carton.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

**PRESENTATION OF ABILIFY:**

ABILIFY tablets are available in aluminium/aluminium blister packs containing 30 or 100 tablets.

**IDENTIFICATION OF ABILIFY TABLETS:**

ABILIFY 5 mg tablets are: blue, modified, rectangular, debossed on one side with "A-007" and "5"

ABILIFY 10 mg tablets are: pink, modified rectangular tablets, debossed on one side with "A-008" and "10"

ABILIFY 15 mg tablets are: yellow, round tablets, debossed on one side with "A-009" and "15"

**REGISTRATION NUMBER:**

**ABILIFY 5 mg:** A41/2.6.5/0493

**ABILIFY 10 mg:** A38/2.6.5/0595

**ABILIFY 15 mg:** A38/2.6.5/0596

**NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:**

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**DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:**

April 2017