

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### ABILIFY 7.5 mg/ml solution for injection aripiprazole

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

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## **1. WHAT ABILIFY IS AND WHAT IT IS USED FOR**

**ABILIFY is one of a group of medicines called antipsychotics.**

ABILIFY solution for injection is used to treat quickly symptoms of agitation and distressing behaviour that may occur in a disease characterised 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.
- feeling "high", having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability.

ABILIFY solution for injection is given when treatment with oral formulations of ABILIFY is not appropriate. Your doctor will change your treatment to ABILIFY tablets, ABILIFY orodispersible tablets or ABILIFY oral solution as soon as appropriate.

## **2. BEFORE YOU USE ABILIFY**

### **Do not use ABILIFY**

- if you are allergic (hypersensitive) to aripiprazole or any of the other ingredients of ABILIFY.

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

Before treatment with ABILIFY, 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
- Seizure
- 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, as antipsychotics have been associated with formation of blood clots

If you notice you are gaining weight, experience any difficulty in swallowing or allergic symptoms, please tell your doctor.

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.

Tell the doctor or nurse if you feel dizzy or faint after the injection. You will probably need to lie down until you feel better. The doctor may also want to measure your blood pressure and pulse.

Tell your doctor immediately if you are having any thoughts or feelings about hurting yourself. Suicidal thoughts and behaviours have been reported during aripiprazole treatment.

Tell your doctor immediately if you suffer from muscle stiffness or inflexibility with high fever, sweating, altered mental status, or very rapid or irregular heart beat.

### **Children and adolescents**

ABILIFY solution for injection is not for use in children and adolescents under 18 years. Ask your doctor or pharmacist for advice before taking ABILIFY.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Blood pressure-lowering medicines: 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

A combination of ABILIFY solution for injection with medicines taken for anxiety might make you feel drowsy or dizzy. Only take other medicines while you are on ABILIFY if your doctor tells you that you can.

### **Using 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** unless you have discussed this with your doctor. Be sure to tell your doctor immediately if you are pregnant, think you may be pregnant, or if you are planning to become pregnant.

### **Be sure to tell your doctor immediately if you are breast-feeding.**

If you are taking ABILIFY, you should not breast-feed.

### **Driving and using machines**

Do not drive or use any tools or machines if you feel drowsy after receiving ABILIFY solution for injection.

## **3. HOW TO USE ABILIFY**

Your doctor will decide how much ABILIFY solution for injection you need and how long you need it for. The usual dose is 9.75 mg (1.3 ml) for the first injection. Up to three injections in 24 hours may be given. The total dose of ABILIFY (all formulations) should not exceed 30 mg per day.

ABILIFY solution for injection is ready to use. The correct amount of solution will be injected into your muscle by your doctor or nurse.

**If you are concerned that you are given more ABILIFY solution for injection than you feel necessary, tell your doctor or nurse of your concern. Only a few doses of ABILIFY solution for injection may be needed. Your doctor will decide when you need another dose of ABILIFY solution for injection.**

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

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, ABILIFY can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention:

very common:	affects more than 1 user in 10
common:	affects 1 to 10 users in 100
uncommon:	affects 1 to 10 users in 1,000
rare:	affects 1 to 10 users in 10,000
very rare:	affects less than 1 user in 10,000
not known:	frequency cannot be estimated from the available data

**Common side effects** of ABILIFY solution for injection include sleepiness, dizziness, headache, restlessness, nausea and vomiting.

**Uncommon side effects:** some people may have changes in blood pressure, may feel dizzy, especially when getting up from a lying or sitting position, or may experience a fast heart rate, dry mouth or fatigue.

**In addition, the following side effects have been seen in patients treated with oral formulations of ABILIFY:**

**Common side effects:** uncontrollable twitching or jerking movements, headache, tiredness, nausea, vomiting, an uncomfortable feeling in the stomach, constipation, increased production of saliva, light-headedness, trouble sleeping, restlessness, feeling anxious, sleepiness, shaking and blurred vision.

**Uncommon side effects:** some people may feel dizzy, especially when getting up from a lying or sitting position, or may experience a fast heart rate.  
Some people may feel depressed.

The following side effects have been reported since the marketing of ABILIFY but the frequency for them to occur is not known:

Changes in the levels of some blood cells; unusual heart beat, sudden unexplained death, heart attack; allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching, rash); high blood sugar, onset or worsening of diabetes, ketoacidosis (ketones in the blood and urine) or coma, low sodium level in the blood; weight gain, weight loss, anorexia; nervousness, agitation, feeling anxious; thoughts of suicide, suicide attempt and suicide; speech disorder, seizure, combination of fever, muscle stiffness, faster breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate; fainting, high blood pressure, blood clots in the veins especially in the legs (symptoms

include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing (if you notice any of these symptoms, seek medical advice immediately); spasm of the muscles around the voice box, accidental inhalation of food with risk of pneumonia, difficulty in swallowing; inflammation of the pancreas; inflammation of the liver, yellowing of the skin and white part of eyes, reports of abnormal liver test values, abdominal and stomach discomfort, diarrhoea; skin rash and sensitivity to light, unusual hair loss or thinning, excessive sweating; stiffness or cramps, muscle pain, weakness; involuntary loss of urine, difficulty in passing urine; prolonged and/or painful erection; difficulty controlling core body temperature or overheating, chest pain, and swelling of hands, ankles or feet.

Adolescents 15 years and older experienced side effects that were similar in frequency and type to those in adults except that sleepiness and uncontrollable twitching or jerking movements were very common (greater than 1 in 10 patients) and dry mouth, increased appetite, and feeling dizzy, especially when getting up from a lying or sitting position, were common.

In elderly patients with dementia, more fatal cases have been reported while taking aripiprazole. In addition, cases of stroke or "mini" stroke have been reported.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, **please tell your doctor or pharmacist.**

## **5. HOW TO STORE ABILIFY**

**Keep out of the reach and sight of children.**

Do not use ABILIFY after the expiry date which is stated on the carton and on the vial.

Keep the vial in the outer carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What ABILIFY contains**

- The active substance is aripiprazole. Each ml contains 7.5 mg aripiprazole. A vial contains 9.75 mg (1.3 ml) aripiprazole.
- The other ingredients are sulfobutylether  $\beta$ -cyclodextrin (SBECD), tartaric acid, sodium hydroxide, and water for injections.

### **What ABILIFY looks like and contents of the pack**

The ABILIFY solution for injection is a clear, colourless, aqueous solution.

Each carton contains one single-use type I glass vial with a rubber butyl stopper and a "flip-off" aluminium seal.

### **Marketing Authorisation Holder**

Otsuka Pharmaceutical Europe Ltd.  
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**This leaflet was last approved in**

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu/>