

PACKAGE LEAFLET: INFORMATION FOR THE USER

ABILIFY 15 mg orodispersible tablets 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.

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1. What ABILIFY is and what it is used for
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1. WHAT ABILIFY IS AND WHAT IT IS USED FOR

ABILIFY is one of a group of medicines called antipsychotics.

It is used to treat adults and adolescents 15 years and older who suffer from 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.

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. It also prevents this condition from returning in patients who have responded to the treatment with ABILIFY.

2. BEFORE YOU TAKE ABILIFY

Do not take 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 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 is not for use in children and adolescents under 15 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

Taking ABILIFY with food and drink

ABILIFY can be taken regardless of meals.

Alcohol should be avoided when taking ABILIFY.

Pregnancy and breast-feeding

You should not take 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, until you know how ABILIFY affects you.

Important information about some of the ingredients of ABILIFY

Patients who cannot take phenylalanine should note that ABILIFY orodispersible tablets contain aspartame, which is a source of phenylalanine. **May be harmful for people with phenylketonuria.**

3. HOW TO TAKE ABILIFY

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

Adults:

- **The usual dose for adults 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.

Use in children:

- For **adolescents 15 years and older**, ABILIFY may be started at a low dose with the oral solution (liquid) form. The dose may be gradually increased to the usual dose for adolescents of 10 mg once a day. However your doctor may prescribe a lower or higher dose to a maximum of 30 mg once a 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 orodispersible tablet at the same time each day. It does not matter whether you take it with or without food.

Do not open the blister until ready to administer. For single tablet removal, open the package and peel back the foil on the blister to expose the tablet. Do not push the tablet through the foil because this could damage the tablet. Immediately upon opening the blister, using dry hands, remove the tablet and place the entire orodispersible tablet on the tongue. Tablet disintegration occurs rapidly in saliva. The orodispersible tablet can be taken with or without liquid.

Alternatively, disperse the tablet in water and drink the resulting suspension.

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 orodispersible tablets than your doctor has recommended (or if someone else has taken some of your ABILIFY orodispersible 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.

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: 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 blister and on the carton.

Store in the original package in order to protect from moisture.

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 orodispersible tablet contains 15 mg of aripiprazole.
- The other ingredients are calcium silicate, croscarmellose sodium, crospovidone, silicon dioxide, xylitol, microcrystalline cellulose, aspartame, acesulfame potassium, vanilla flavour, tartaric acid, magnesium stearate, yellow iron oxide (E172).

What ABILIFY looks like and contents of the pack

ABILIFY 15 mg orodispersible tablets are round and yellow, marked with "A" over "641" on one side and '15' on the other. They are supplied in perforated unit dose blisters packed in cartons containing 14, 28, or 49 orodispersible tablets.

Not all pack sizes may be marketed.

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