



EUROPEAN MEDICINES AGENCY  
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## EPAR summary for the public

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# Abilify

## aripiprazole

This is a summary of the European public assessment report (EPAR) for Abilify. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Abilify.

For practical information about using Abilify, patients should read the package leaflet or contact their doctor or pharmacist.

### What is Abilify and what is it used for?

Abilify is an antipsychotic medicine for patients with schizophrenia and bipolar I disorder.

In schizophrenia, a mental illness with symptoms such as delusions, disorganised speech, and hallucinations (hearing or seeing things that are not there), Abilify is used to treat patients from the age of 15 years.

In bipolar I disorder, Abilify is used in adults to treat manic episodes (periods of abnormally high mood) and to prevent new ones in those who have responded to the medicine in the past. It can also be used for up to 12 weeks to treat manic episodes in adolescents from the age of 13 years.

Abilify contains the active substance aripiprazole.

### How is Abilify used?

Abilify is available as tablets and a liquid to be taken by mouth. It is also available as a solution for injection into the shoulder or buttock muscle. The injection is used only for quickly controlling agitation or disturbed behaviour in patients with schizophrenia or bipolar I disorder. For information on the dose and dose adjustments, see the package leaflet.

Abilify can only be obtained with a prescription.



## How does Abilify work?

The active substance in Abilify is aripiprazole. The exact way it works is not known but it attaches in the brain to receptors for two substances (neurotransmitters) called dopamine and serotonin (5HT), which are believed to play a role in schizophrenia and bipolar disorder. By attaching to these receptors, it is thought that aripiprazole helps normalise the activity of the brain, reducing psychotic or manic symptoms and preventing them from returning.

## What benefits of Abilify have been shown in studies?

### Schizophrenia

Studies showed that Abilify is effective at treating symptoms of schizophrenia using standard rating scales (such as the Positive and Negative Syndrome Scale, PANSS).

In studies of 1,203 adults, Abilify was more effective than placebo (a dummy treatment) at reducing symptoms. In another adult study, Abilify was as effective as haloperidol, another antipsychotic medicine, in preventing symptoms from returning over 1 year.

Abilify has also been studied in 302 adolescents aged between 13 and 17, with results showing Abilify to be more effective than placebo.

A study in 544 patients treated by injection for agitation and disturbed behaviour showed that improvement with Abilify over 24 hours was greater than with placebo and similar to that with haloperidol.

### Bipolar I disorder

Studies in bipolar I disorder showed that Abilify is effective at treating manic episodes using standard measurements such as the Young-Mania Rating Scale (YMRS) scale.

In 4 out of 5 studies in 1,900 adults, Abilify was more effective than placebo at reducing manic symptoms, with two of these studies showing that Abilify has a similar effect to haloperidol and to lithium. Other studies showed that Abilify was more effective than placebo at preventing manic episodes in previously treated adults for up to 74 weeks, and when it was used as an add-on to existing treatment.

A study in 296 children and adolescents showed that Abilify was more effective than placebo at reducing the manic symptoms in patients aged 13 years and older.

Finally, a study in 291 patients treated by injection for agitation and disturbed behaviour showed that improvement with Abilify was greater after 2 hours than with placebo and similar to that with lorazepam (another medicine for treating agitation).

## What is the risk associated with Abilify?

In adults, the most common side effects when taking Abilify by mouth (occurring in up to 10 patients in 100) are restlessness, difficulty sleeping, anxiety, extrapyramidal disorder (uncontrolled twitching or jerking), akathisia (a constant urge to move), tremor (shaking), dizziness, sleepiness, headache, blurred vision, dyspepsia (heartburn), vomiting, nausea (feeling sick), constipation, salivary hypersecretion (increased production of saliva), tiredness and diabetes. The side effects are similar in adolescents, but sleepiness, extrapyramidal disorder, akathisia and tiredness are very common in this group (in more than 1 in 10 adolescents).

The most common side effects with the injection (occurring in up to 10 patients in 100) are sleepiness, dizziness and nausea. For the full list of all side effects and restrictions, see the package leaflet.

### **Why is Abilify approved?**

Studies comparing Abilify to placebo or other medicines (such as haloperidol and lithium) show that Abilify is effective at reducing symptoms of schizophrenia and at treating and preventing high moods in patients with bipolar I disorder.

In addition, the injection has been shown to be effective at quickly controlling agitation or disturbing behaviour in patients with schizophrenia or bipolar I disorder.

With regard to safety, the medicine has side effects comparable to those of other antipsychotics. The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that the benefits of Abilify are greater than its risks and recommended its approval in the EU.

### **What measures are being taken to ensure the safe and effective use of Abilify?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Abilify have been included in the summary of product characteristics and the package leaflet.

### **Other information about Abilify**

The European Commission granted a marketing authorisation valid throughout the European Union for Abilify on 4 June 2004.

The full EPAR for Abilify can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Abilify, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2016.