



15 September 2016
EMA/616984/2016
EMA/H/C/000471

Questions and answers

Application to extend use of Abilify in schizophrenia to 13 and 14 year olds

On 15 September 2016, the Committee for Medicinal Products for Human Use (CHMP) concluded the review of an application to extend the use of Abilify in schizophrenia to adolescents aged 13 and 14 years. The CHMP did not consider the data supporting the application sufficient to recommend extending the medicine's use. However, the Committee considered that the data could be important for healthcare professionals and recommended their inclusion in Abilify's product information.

What is Abilify?

Abilify is a medicine for treating schizophrenia and bipolar disorder. For schizophrenia it is currently approved only for patients aged 15 years and over.

Abilify contains the active substance aripiprazole.

What was Abilify expected to be used for?

The company that markets Abilify applied for it to be used to treat schizophrenia in patients aged 13 years and over.

How does Abilify work?

The active substance in Abilify, aripiprazole, is an antipsychotic medicine. Its exact mechanism of action is unknown, but it is believed to work through several different receptors in the brain, where it partially mimics or blocks the action of the neurotransmitters dopamine and 5-hydroxytryptamine (also called serotonin). Because these neurotransmitters are involved in schizophrenia and bipolar disorder, aripiprazole can help to normalise their activity in the brain, reducing psychotic or manic symptoms and preventing them from returning.



What did the company present to support its application?

The company presented data from a main study in which 146 adolescents with schizophrenia whose symptoms were stable received either Abilify or placebo (a dummy treatment) for one year. Around a fifth of the patients were aged 13 and 14 years. The study investigated how effectively Abilify prevented a relapse of their symptoms.

What was the conclusion of the CHMP?

Although the relapse rate with Abilify in 13 and 14 year olds was similar to the rate in older children (21% and 19% respectively), the number of patients in the main study was too small to draw firm conclusions in the younger group. The CHMP therefore concluded that Abilify could not be approved for schizophrenia in 13 and 14 year olds on the basis of these data.

However, the CHMP noted that schizophrenia is rare in younger patients and that including the data in Abilify's product information could help the healthcare professionals who manage them.

What are the consequences for patients in clinical trials?

There are no consequences of the outcome of this application on patients currently in or who may be joining clinical trials with Abilify. If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.

What is happening with Abilify for the treatment of other diseases?

There are no consequences on the use of Abilify in bipolar disorder or its currently approved use in patients with schizophrenia aged 15 years and over.

More information about Abilify is available on [EMA's website](#).