



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Abilify Maintena (*aripiprazole*)

An overview of Abilify Maintena and why it is authorised in the EU

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

Abilify Maintena is an antipsychotic medicine that contains the active substance aripiprazole. It is used for the maintenance treatment of schizophrenia in adults whose disease has already been stabilised with aripiprazole taken by mouth.

Schizophrenia is a mental illness with a number of symptoms, including disorganised thinking and speech, hallucinations (hearing or seeing things that are not there), suspiciousness and delusions (false beliefs).

### How is Abilify Maintena used?

Abilify Maintena is available as a powder and solvent to be made into a prolonged-release suspension for injection. 'Prolonged release' means that the active substance is released slowly over a few weeks after being injected. The medicine is given once a month by slow injection into the buttock or deltoid (shoulder) muscle by a doctor or nurse. It must not be injected into a vein or under the skin.

The recommended dose depends on whether the patient is taking other medicines that slow the breakdown of aripiprazole in the body and may be reduced if the patient experiences side effects. Treatment beyond 2 weeks with medicines that speed up the breakdown of aripiprazole should be avoided. The first treatment consists of either one injection followed by aripiprazole taken by mouth daily for 2 weeks or two injections and a single dose of aripiprazole by mouth on the same day.

The medicine can only be obtained with a prescription.

### How does Abilify Maintena work?

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



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

Abilify Maintena was shown to be as effective as aripiprazole taken by mouth at preventing symptoms of schizophrenia from returning. In one main study involving adults whose disease had already been stabilised with aripiprazole taken by mouth, 22 out of the 265 patients (8.3%) treated with Abilify Maintena had symptoms coming back within 26 weeks, compared with 21 out of 266 (7.9%) patients treated with aripiprazole taken by mouth.

## **What are the risks associated with Abilify Maintena?**

The most common side effects with Abilify Maintena (which may affect 5 or more people in 100) are increased weight, akathisia (a constant urge to move), insomnia (difficulty sleeping) and injection site pain. For the full list of all side effects reported with Abilify Maintena, see the package leaflet.

## **Why is Abilify Maintena authorised in the EU?**

Abilify Maintena is as effective as aripiprazole taken by mouth and has a similar safety profile with the exception of injection pain, which was considered manageable. The monthly administration may help patients adhere to their treatment. The European Medicines Agency therefore decided that Abilify Maintena's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Abilify Maintena are continuously monitored. Side effects reported with Abilify Maintena are carefully evaluated and any necessary action taken to protect patients.

## **Other information about Abilify Maintena**

Abilify Maintena received a marketing authorisation valid throughout the EU on 15 November 2013.

Further information on Abilify Maintena can be found on the Agency's website:  
[ema.europa.eu/medicines/human/EPAR/abilify-maintena](http://ema.europa.eu/medicines/human/EPAR/abilify-maintena)

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