



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

London 21 March 2013  
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Committee for Medicinal Products for Human Use (CHMP)

Abilify  
(Aripiprazole)

Procedure no. EMEA/H/C/000471/PSU 063

**Scientific conclusions and grounds recommending the variation to the  
terms of the Marketing Authorisations**



## Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Abilify, the scientific conclusions of PRAC are as follows:

- In view of the incidence of hepatic injury and related adverse events, the PRAC recommended inclusion of hepatic failure as an adverse reaction.
- In some of the cases of serotonin syndrome that had diagnostic criteria (Sternbach and / or Hunter criteria), it is not possible to exclude a causal relationship with exposure to aripiprazole due to a positive temporality, positive dechallenge, biological plausibility and even a positive rechallenge. Acknowledging the possibility that other drugs may somehow have contributed to the emergence of adverse events, the PRAC considered relevant to include in the Summary of Product Characteristics, serotonin syndrome as an adverse reaction and to add information about the potential related interaction when adding drugs that may otherwise interfere with uptake and serotonin reuptake inhibitors, such as selective serotonin reuptake inhibitors.
- The PSUR described 3 cases with documented detection of aripiprazole in the breast milk. No adverse effects related to aripiprazole exposure through breast milk exposure were reported in any of the 3 cases. Information is also included regarding excretion of aripiprazole in human breast milk. Nevertheless, further assessment on the implications of presence of aripiprazole in breast milk is required, and therefore the Marketing Authorisation Holder is requested to present more data on the clinical implications of exposure to aripiprazole in newborns via the breast milk.

The CHMP agrees with the scientific conclusions made by the PRAC.

### **Grounds recommending the variation to the terms of the Marketing Authorisation**

On the basis of the scientific conclusions for Abilify, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance aripiprazole is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms to the Marketing Authorisation should be varied.