

On June 19, 2003, the Food and Drug Administration (FDA) recommended that Paxil(c) (paroxetine hydrochloride) not be used in children and adolescents under the age of 18. In children and adolescents, Paxil(c) is usually used for the treatment of major depressive disorder (MDD). It is essential that children and adolescents do not stop taking Paxil(c) without first consulting with their treating physician. The FDA advisory warns against abrupt discontinuation.

There have been reports of a possible increased risk of suicidal ideation and suicide attempts in children and adolescents taking Paxil(c) for depression. The increased risk has not been indicated for adults.

The FDA advisory follows a June 10th advisory from the United Kingdom (UK) Department of Health. The decision was made after Paxil(c) (called Seroxat in the U.K.) manufacturer GlaxoSmithKline submitted data involving more than 1,000 pediatric patients taking Paxil for depression. Investigators found that suicidal thoughts and attempts were roughly twice as high among children and adolescents taking Paxil(c) than among those taking a placebo (3.2% vs. 1.5%). (From the UK's Medicines and Healthcare Products Regulatory Agency.)

- For the FDA's statement regarding the anti-depressant Paxil(c) for the pediatric population, please visit: www.fda.gov/cder/drug/infopage/paxil/paxilQ&A.htm#q1
- For the FDA's questions and answers on Paxil(c), please visit: <http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01230.html>
- To view the United Kingdom's Department of Health's Chairman of Committee on Safety of Medicine's message on paroxetine hydrochloride for the pediatric population, please visit: www.mca.gov.uk