

Birth Control Pills Containing Drospirenone: Possible Increased Risk of Blood Clots

UPDATED 09/26/2011] FDA has not yet reached a conclusion, but remains concerned, about the potential increased risk of blood clots with the use of drospirenone-containing birth control pills. FDA has completed its review of the two 2011 studies that evaluated the risk of blood clots for women who use drospirenone-containing birth control pills. FDA is continuing its review of a separate FDA-funded study that evaluated the risk of blood clots in users of several different hormonal birth control products (contraceptives). Preliminary results of the FDA-funded study suggest an approximately 1.5-fold increase in the risk of blood clots for women who use drospirenone-containing birth control pills compared to users of other hormonal contraceptives.

Given the conflicting nature of the findings from six published studies evaluating this risk, as well as the preliminary data from the FDA-funded study FDA has scheduled a joint meeting of the Reproductive Health Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee on December 8, 2011 to discuss the risks and benefits and specifically the risk of blood clots of drospirenone-containing birth control pills.