

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

**ISSUE:** FDA is aware of two newly published studies that evaluated the risk of venous thromboembolism (VTE) in women who use birth control pills that contain drospirenone. The two recently published studies looked at whether there is a higher risk of blood clots in women taking birth control pills containing the progestin drospirenone when compared to similar women taking birth control pills containing a different progestin called levonorgestrel. These two new studies reported that there is a greater risk of VTE associated with birth control pills that contain drospirenone. This risk is reported to be up to 2 to 3 times greater than the risk of VTE associated with using levonorgestrel-containing pills. Other studies have not reported an increase in risk. The FDA is currently evaluating the conflicting results from these studies and will look at all currently available information to fully assess the risks and benefits of drospirenone-containing birth control pills. FDA will continue to communicate any new safety information to the public as it becomes available. Read the drug safety communication for more information on these studies.

**BACKGROUND:** Drospirenone is a type of female sex hormone called a progestin. Most birth control pills contain two types of hormones--estrogen and progestin. Birth control pills work by preventing the release of eggs from the ovaries (ovulation) and changing the cervical mucus and the lining of the uterus to prevent pregnancy. Brand names of drospirenone-containing products include Yaz (generics Gianvi and Loryna), Yasmin (generics Ocella, Syeda, and Zarah), Beyaz, and Safyral.

**RECOMMENDATION:** If your birth control pill contains drospirenone, do not stop taking it without first talking to your healthcare professional. Contact your healthcare professional immediately if you develop any symptoms of blood clots, including persistent leg pain, severe chest pain, or sudden shortness of breath. If you smoke and are over 35 years of age, you should not take combination oral contraceptives because they increase the risk that you could experience serious cardiovascular events, including blood clots.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- [Download form](#)<sup>1</sup> or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178