Birth Control Pills Containing Drospirenone: Label Change-Products may be associated with a higher risk for blood clots

U.S. Food & Drug Administration

ISSUE: FDA has completed its review of recent observational (epidemiologic) studies regarding the risk of blood clots in women taking drospirenone-containing birth control pills.Based on this review, FDA has concluded that drospirenone-containing birth control pills may be associated with a higher risk for blood clots than other progestin-containing pills.

BACKGROUND: Drospirenone is a synthetic version of the female hormone, progesterone, also referred to as a progestin. FDA is adding information about the studies to the labels of drospirenone-containing birth control pills.

The revised drug labels will report that some epidemiologic studies reported as high as a three-fold increase in the risk of blood clots for drospirenone-containing products when compared to products containing levonorgestrel or some other progestins, whereas other epidemiological studies found no additional risk of blood clots with drospirenone-containing products. The labels also will include a summary of the previously released results of an FDA-funded study of the blood clot risk.

RECOMMENDATION: Women should talk to their healthcare professional about their risk for blood clots before deciding which birth control method to use.

Healthcare professionals should consider the risks and benefits of drospirenone-containing birth control pills and a woman’s risk for developing a blood clot before prescribing these drugs.

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 [1]
- Download form [2] 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

[04/10/2012 - Drug Safety Communication [3] - FDA]

Previous MedWatch Alert:

[10-27-2011 [4]]

SOURCE [5]

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http://www.mdtmag.com/news/2012/04/birth-control-pills-containing-drospirenone-label-change-products-may-be-associated-higher-risk-blood-clots

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[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
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