

FDA Drug Safety Communication:

Updated information about the risk of blood clots in women taking birth control pills containing drospirenone [10/4/2012]

The U.S. Food and Drug Administration (FDA) has completed its review of recent observational (epidemiologic) studies regarding the risk of blood clots in women taking drospirenone-containing birth control pills. Drospirenone is a synthetic version of the female hormone, progesterone, also referred to as a progestin. 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. FDA is adding information about the studies to the labels of drospirenone-containing birth control pills.

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.

The studies reviewed did not provide consistent estimates of the comparative risk of blood clots between birth control pills that contain drospirenone and those that do not. The studies also did not account for important patient characteristics (known and unknown) that may influence prescribing and that likely affect the risk of blood clots. For these reasons, it is unclear whether the increased risk seen for blood clots in some of the epidemiologic studies is actually due to drospirenone-containing birth control pills.

The revised drug labels (Beyaz, Safyral, Yasmin and Yaz) 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.

To put the risk of developing a blood clot from a birth control pill into perspective:

The risk of blood clots is higher when using any birth control pills than not using them, but still remains lower than the risk of developing blood clots in pregnancy and in the postpartum period.

Source : <http://www.fda.gov/Drugs/DrugSafety/ucm299305.htm?source=govdelivery>

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