

Certain birth control pills may carry higher blood clot risk: FDA

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Products such as Yaz or Yasmin, containing drospirenone, will get new labels, agency says.

(HealthDay) -- U.S. health officials announced Tuesday that birth controls pills containing drospirenone -- a man-made version of the hormone progesterone -- may be associated with a higher risk of blood clots and will require new labels.

The U.S. Food and Drug Administration said the updated labels will inform users that the pills -- which include products such as Bayer's Yaz or Yasmin -- may carry as much as a tripled risk for blood clots compared to <u>birth control pills</u> containing other types of progesterone (also called progestins) such as levonorgestrel.

The agency findings came from observational studies, some of which found increased risk for blood clots while others did not, the FDA noted in its <u>medication safety</u> alert.



The decision follows recommendations made in December by an FDAappointed panel that several drospirenone-containing contraceptives carry revised labels warning about an increased risk of potentially fatal blood clots.

The FDA advisers had voted 21-5 in favor of new labels for the <u>oral</u> <u>contraceptives</u>. These newer contraceptives have been successfully marketed on the premise that they have fewer of the unwanted side effects of older <u>hormone pills</u> such as bloating, mood swings and acne.

Dr. Tara Narula, a cardiologist at Lenox Hill Hospital in New York City, told *HealthDay* in December that the risk of clotting with the newer pills is "a low risk but the risk exists. The idea of the FDA looking at this and potentially increasing the warning has no downside. If anything, it increases awareness and that can only be a good thing."

Previously, the panel members had voted that the newer contraceptives, which gained initial FDA approval in 2001, are a viable method of birth control, and that the benefits of preventing pregnancy outweigh the health risks.

More information: The U.S. Department of Health and Human Services has more about birth control at <u>womenshealth.gov</u>.

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