

## Some birth control shows higher clot risk: US

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Some birth control products, including contraceptive pills, rings and patches for women, carry a significantly higher risk of blood clot than low-dose medications, US regulators said Thursday.

The US <u>Food and Drug Administration</u> said in its review of studies that have included more than 800,000 women that the higher risks are posed by products such as the pill Yaz, the transdermal Ortho Evra patch, and the NuvaRing vaginal insert.

All three methods are "associated with an increased risk of VTE (deep venous thrombosis) relative to the standard low-dose" pills, the FDA said.

Featured in the study were pills that contain drospirenone, as opposed to another type of progestin known as levonorgestrel. Some brand names include Yaz, Yasmin, Beyaz, Ocella, Loryna, Gianvi, Safyral, Syeda and Zarah.

Yaz is the second biggest selling product made by the German pharmaceutical giant Bayer, with 1.56 billion in global sales.

NuvaRing is a once-a-month vaginal insert made by Merck pharmaceuticals, and the weekly Ortho Evra patch is made by Janssen Pharmaceuticals.

The finding about clot risk associated with patches and rings are new and need to be replicated, the FDA said. A full discussion on the matter is



scheduled for December.

These "continuous exposure" <u>birth control</u> methods "potentially result in higher sustained exposure to estrogen and hence, increased thromboembolic risk," the FDA warned.

The European Medicines Agency concluded on May 27 that such <u>birth</u> <u>control pills</u> carry a higher risk of venous thromboembolism and that <u>warning labels</u> should be updated accordingly.

However it noted the overall risk of blood clot from any birth control method remains small and stopped short of advising women to stop taking pills containing drospirenone.

The pills have been the focus of numerous lawsuits, including one lodged earlier this year on behalf of a teenager who died from a blood clot allegedly linked to the German chemical and pharmaceutical company Bayer's Yaz contraceptive.

Michelle Pfleger, an 18-year-old college student in North Carolina, died of cardiac arrest last September after taking Yaz, also known as Yasmin or Ocella, to treat acne, according to the complaint.

Two studies out this year in the British Medical Journal found that drugs like Yaz and Yasmin increase the risk of serious blood clots three-fold or two-fold compared to earlier-generation oral contraceptives.

The official Yaz website says the drug is associated with "increased risks of several serious side effects, including <u>blood clots</u>, stroke, and heart attack."

According to Glenn Jacobowitz, vice-chair of the division of vascular surgery at New York University, doctors have been aware of the risks of



Yaz and similar pills for some time.

"The information on NuvaRing and Ortho Evra would be a new, but similar finding. This is certainly worrisome, particularly for women over age 35 and for smokers," he said.

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