



U.S. Food & Drug Administration

Drugs

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## FDA Drug Safety Communication: Updated information about the risk of blood clots in women taking birth control pills containing drospirenone

This update is in follow-up to the [FDA Drug Safety Communication posted on 9/26/11](#): <sup>1</sup> Safety review update on the possible increased risk of blood clots with birth control pills containing drospirenone.

### Safety Announcement

**[4-10-2012]** 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. See [Table 1](#) for a list of drospirenone-containing products.

**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.**

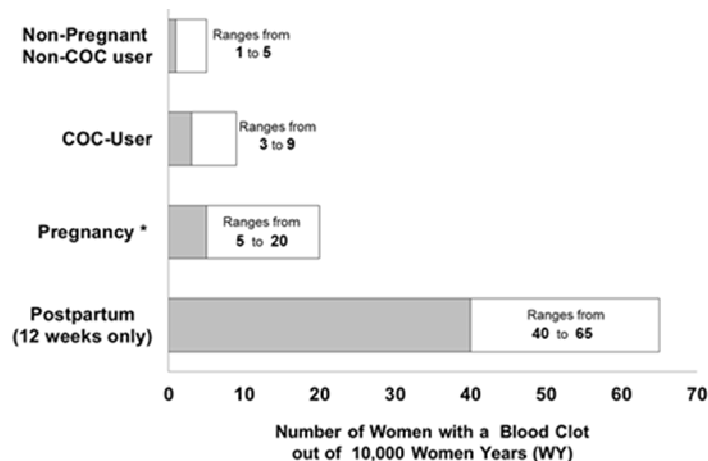
The studies reviewed did not provide consistent estimates of the comparative risk of blood clots between birth control pills that contain drospirenone and those that do not. The studies also did not account for important patient characteristics (known and unknown) that may influence prescribing and that 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](#)<sup>2</sup>, [Safyral](#)<sup>3</sup>, [Yasmin](#)<sup>4</sup> and [Yaz](#)<sup>5</sup>) 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](#)<sup>6</sup>.

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.

Figure 1 shows the risk of developing a blood clot for women who are not pregnant and do not use birth control pills; for women who use birth control pills; for pregnant women; and for women in the postpartum period. For example: If 10,000 women who are not pregnant and do not use birth control pills are followed for one year, between 1 and 5 of these women will develop a blood clot.

**Figure 1: Likelihood of Developing a Blood Clot**



\* Pregnancy data based on actual duration of pregnancy in the reference studies. Based on a model assumption that pregnancy duration is nine months, the rate is 7 to 27 per 10,000 WY.

COC = combination oral contraceptives or birth control pills

These studies were discussed at the joint meeting of the FDA's Reproductive Health Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee on December 8, 2011. FDA's briefing document for this meeting is found [here](#)<sup>7</sup>.

Previous Drug Safety Communications related to the risk of blood clots with birth control pills that contain drospirenone were posted on [May 31, 2011](#)<sup>8</sup>, [September 26, 2011](#)<sup>9</sup>, and [October 27, 2011](#)<sup>10</sup>. The DSC posted in May 2011 updated the public about FDA's ongoing safety review of two new studies that reported a greater risk of blood clots for women taking drospirenone-containing products as compared to the risk in women taking products containing other progestins. Previously published studies had reported conflicting findings. The DSC posted in September 2011 discussed preliminary results from a FDA-funded study suggesting an approximately 1.5-fold increase in the risk of blood clots for women who use drospirenone-containing products compared to users of other hormonal contraceptives. The DSC posted in October 2011 released the final study report and appendices from the FDA-funded study in advance of the Joint Meeting of the Drug Safety and Risk Management Advisory Committee and Reproductive Health Drugs Advisory Committee Meeting.

Today's communication is in keeping with FDA's commitment to inform the public about the Agency's ongoing safety review of drugs. FDA will communicate any new information on drospirenone-containing birth control pills and the risk of blood clots when it becomes available.

**Table 1. Approved Oral Contraceptives Containing Drospirenone**

Brand name	Generic name
Beyaz	Drospirenone 3 mg, ethinyl estradiol 0.02 mg and levomefolate calcium 0.451 mg
Drospirenone and ethinyl estradiol	Drospirenone 3 mg and ethinyl estradiol 0.03 mg
Drospirenone and ethinyl estradiol	Drospirenone 3 mg and ethinyl estradiol 0.02 mg
Gianvi	Drospirenone 3 mg and ethinyl estradiol 0.02 mg
Loryna	Drospirenone 3 mg and ethinyl estradiol 0.02 mg
Ocella	Drospirenone 3 mg and ethinyl estradiol 0.03 mg
Safyral	Drospirenone 3 mg, ethinyl estradiol 0.03 mg, and levomefolate calcium 0.451 mg
Syeda	Drospirenone 3 mg and ethinyl estradiol 0.03 mg
Yasmin	Drospirenone 3 mg and ethinyl estradiol 0.03 mg
Yaz	Drospirenone 3 mg and ethinyl estradiol 0.02 mg
Zarah	Drospirenone 3 mg and ethinyl estradiol 0.03 mg

**Related Information**

- [Updated External Questions and Answers – Ongoing safety review of birth control pills containing drospirenone and a possible increased risk of blood clots](#)<sup>11</sup>  
4-10-2012
- [Beyaz Label](#)<sup>12</sup>  
4-10-2012
- [Safyral Label](#)<sup>13</sup>
- [Yasmin Label](#)<sup>14</sup>  
4-10-2012
- [Yaz Label](#)<sup>15</sup>
- [FDA Drug Safety Communication: Safety review update on the possible increased risk of blood clots with birth control pills containing drospirenone](#)<sup>16</sup>  
9-26-2011
- [FDA Drug Safety Communication: Updated information about the FDA-funded study on risk of blood clots in women taking birth control pills containing drospirenone](#)<sup>17</sup>  
10-27-2011
- [FDA Drug Safety Communication: Safety Review of possible increased risk of blood clots with birth control pills containing drospirenone](#)<sup>18</sup>  
5-31-2011
- [FDA Briefing Information for the December 8, 2011 Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee \(PDF – 1.86MB\) \(PDF - 5.2MB\)](#)<sup>19</sup>
- [FDA Drug Safety Podcast for Healthcare Professionals: Updated information about the risk of blood clots in women taking birth control pills containing drospirenone](#)<sup>20</sup>

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**Regular Mail:** Use postage-paid [FDA Form 3500](#)<sup>22</sup>

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