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Drugs

FDA Drug Safety Communication: Safety Review of possible increased risk of blood clots with birth control pills containing drospirenone

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Safety Announcement

[05-31-2011] The U.S. Food and Drug Administration (FDA) is informing the public about new information^{1,2} that is being assessed as part of FDA's ongoing safety review of birth control pills that contain drospirenone. This review will further evaluate the risk of blood clots in women who use these products.

Drospirenone is a type of female sex hormone called a progestin. Most birth control pills contain two types of hormones--estrogen and progestin. Birth control pills work by preventing the release of eggs from the ovaries (ovulation) and changing the cervical mucus and the lining of the uterus to prevent pregnancy.

A list of birth control pills that contain drospirenone is [available here](#).

All birth control pills pose a risk of blood clots. Several epidemiological studies have reported that the risk of blood clots for women who use birth control pills containing drospirenone is higher than that for women who use birth control pills containing the progestin levonorgestrel. Other studies have not reported an increase in risk.

A blood clot that forms in a deep vein in the body is called a deep vein thrombosis (DVT). A DVT is a rare side effect of taking birth control pills. A blood clot can break loose from the vein, move through the body to the lung, and cause a serious problem in the lung, called a pulmonary embolism (PE). This can lead to death.³

Two recently published studies reported a greater risk of blood clots for women taking birth control pills containing drospirenone as compared to the risk in women taking birth control pills containing another progestin known as levonorgestrel.^{1,2}

Previously published studies have also addressed the risk of blood clots in women using birth control pills containing drospirenone. These studies had conflicting findings--two postmarketing studies required by the FDA or European regulatory agencies did not report any difference in the risk of blood clots between drospirenone-containing products and products containing levonorgestrel or other progestins.^{4,5} Two other publications in 2009, however, reported that the risk of blood clots is higher in women using drospirenone-containing products than in women who use levonorgestrel-containing products.^{6,7}

Information from these latter four studies is already presented in the Warnings and Precautions section of current labels for drospirenone-containing birth control pills. An additional large study exploring the association of blood clots with hormonal contraception has been commissioned by FDA, and results of that study are currently being finalized and reviewed.

Facts about Drospirenone

- Used in combination with an estrogen in oral contraceptives.
- Brand names of drospirenone-containing products include Yaz (generics Gianvi and Loryna), Yasmin (generics Ocella, Syeda, and Zarah), Beyaz, and Safyral.
- In addition to prevention of pregnancy, some birth control pills containing drospirenone are also approved to treat symptoms of premenstrual dysphoric disorder (PMDD), to treat moderate acne and to raise folate levels, in women who choose to use an oral contraceptive for birth control.

The [European Medicines Agency \(EMA\)](#) announced on May 27, 2011¹, that it is updating the product information on oral contraceptives containing drospirenone and ethinyl estradiol regarding the risk of venous thromboembolism after review of all available data, including the same newly published data FDA is reviewing.

The FDA is currently evaluating the conflicting results from these studies and will look at all currently available information to fully assess the risks and benefits of drospirenone-containing birth control pills. FDA will continue to communicate any new safety information to the public as it becomes available.

Additional Information for Patients

- If your birth control pill contains drospirenone, do not stop taking it without first talking to your healthcare professional.
- Discuss any questions or concerns about your birth control pill with your healthcare professional.
- Know the symptoms of blood clots, including persistent leg pain, severe chest pain, or sudden shortness of breath. Contact your healthcare professional immediately if you develop any of these symptoms.
- If you smoke and are over 35 years of age, you should not take combination oral contraceptives because they increase the risk that you could experience serious cardiovascular events, including blood clots.
- Report any side effects you experience to the FDA MedWatch program using the information in the "Contact Us" box at the bottom of the page.

Additional Information for Healthcare Professionals

- Continue to follow the recommendations in the drug labels when prescribing oral contraceptive products that contain drospirenone.
- Discuss the known benefits and potential risks of drospirenone-containing products with your patients.
- Educate your patients to recognize the signs and symptoms of DVT and PE, and tell them to immediately contact their healthcare professional if they develop any of these symptoms.
- Report adverse events involving drospirenone-containing oral contraceptives to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of the page.

Data Summary

Two recent articles in the *British Medical Journal* have raised the question as to whether there is greater risk of DVT and PE in women taking combination oral contraceptives containing the progestin drospirenone as compared to the risk in women taking oral contraceptives containing the progestin levonorgestrel.^{1,2} These two new studies reported a two- to three-fold greater risk of venous thromboembolic events or VTEs (VTEs include DVTs and PEs) in women using oral contraceptives containing drospirenone rather than levonorgestrel.

Previously published studies have also addressed the risk of blood clots in women using birth control pills containing drospirenone. These studies had conflicting findings. Two were postmarketing studies required by the FDA or European regulatory agencies. These studies did not report any difference in VTE risk between drospirenone-containing products and products containing levonorgestrel or other progestins.^{4,5} However, two other publications from 2009 reported a 1.5- to 2-fold higher VTE risk in women who use drospirenone-containing contraceptives as compared to the risk in women who use levonorgestrel-containing contraceptives.^{6,7} Results of these latter four studies are described in the current labels for all the drospirenone-containing contraceptive products.

FDA is currently reviewing the two most recent studies and will be looking at all currently available information to assess whether there is a greater risk of VTE in women using oral contraceptives containing drospirenone. Data from an additional, large, FDA-funded, study on hormonal contraceptives is also being finalized and reviewed. This study includes over 800,000 US women and is designed to look at thrombotic and thromboembolic risks including VTE in a number of hormonal contraceptive products; results are expected later this summer. FDA will continue to communicate any new safety information to the public as it becomes available.

References

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3. U.S. National Library of Medicine. National Institutes of Health. Health Topics monograph Deep Vein Thrombosis. Available at <http://www.nlm.nih.gov/medlineplus/deepveinthrombosis.html>²; Accessed April 28, 2011.
4. Seeger JD, Loughlin J, Eng PM, Clifford CR, Cutone J, Walker AM. Risk of thromboembolism in women taking ethinylestradiol/drospirenone and other oral contraceptives. *Obstet Gynecol* 2007; 110(3):587-93.
5. Dinger JC, Heinemann LA, Kühl-Habich D. The safety of a drospirenone-containing oral contraceptive: final results from the European Active Surveillance Study on oral contraceptives based on 142,475 women-years of observation. *Contraception* 2007; 75:344-54.
6. Lidegaard Ø, Løkkegaard E, Svendsen AL, Agger C. Hormonal contraception and risk of venous thromboembolism: national follow-up study. *BMJ* 2009; 339:b2890.
7. Van Hylckama V, Helmerhorst FM, Vandenbroucke JP, Doggen CJM, Rosendaal FR. The venous thrombotic risk of oral contraceptives, effects of oestrogen dose and progestogen type: results of the MEGA case-control study. *BMJ* 2009; 339:b2921.

Table 1. Approved Oral Contraceptives containing Drospirenone

Brand name	Generic name
Beyaz	Drospirenone, ethinyl estradiol and levomefolate calcium
Drospirenone and ethinyl estradiol	Drospirenone and ethinyl estradiol
Gianvi	Drospirenone and ethinyl estradiol
Loryna	Drospirenone and ethinyl estradiol
Ocella	Drospirenone and ethinyl estradiol
Safyral	Drospirenone, ethinyl estradiol, and levomefolate calcium
Syeda	Drospirenone and ethinyl estradiol
Yasmin	Drospirenone and ethinyl estradiol
Yaz	Drospirenone and ethinyl estradiol
Zarah	Drospirenone and ethinyl estradiol

Related Information

- [Information about Drospirenone](#)³
- [Questions and Answers – Ongoing safety review of birth control pills containing drospirenone and a possible increased risk of blood clots](#)⁴
- [FDA Drug Safety Podcast for Healthcare Professionals: Safety Review of possible increased risk of blood clots with birth control pills containing drospirenone](#)⁵

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