April 2012 Yasmin / YAZ Label Change: FDA Warns About Increased Risk Of Blood Clots Possible Due To Drospirenone

Beyaz, Safyral, Ocella, Gianvi, Zarah, Loryna, Syeda, And Vestura OC Pills Contain DRSP Progestin Also


On April 10, 2012 the FDA issued "Drug Information Update - Drug Safety Communication: Updated information about the risk of blood clots in women taking birth control pills containing drospirenone", an email alert which initially let us know about a significant revision to the package insert, or drug label, for the following oral contraceptive (OC) pills:

- **YAZ**, **Yasmin**, **Beyaz**, and **Safyral**, which are manufactured by Bayer HealthCare Pharmaceuticals, Inc.;
- **Ocella**, a generic version of Yasmin, and **Gianvi**, a generic version of YAZ. The Ocella and Gianvi birth control pills are from Teva Pharmaceuticals and Barr Laboratories;
- **Zarah**, a generic version of Yasmin, and **Vestura**, a generic version of YAZ. The Zarah and Vestura oral contraceptives are made by Watson Pharmaceuticals; and
- **Loryna**, a generic version of YAZ, and **Syeda**, a generic version of Yasmin. The Loryna and Syeda OCs are made and sold by Sandoz, Inc.

In summary, the FDA has completed its review of some relatively recent medical studies regarding these drospirenone-containing oral contraceptives which was intended to determine whether there was any increased risk of blood clots in women using one of these DRSP OCs. Based on this review, FDA has concluded that Yasmin, YAZ, Safyral, and Beyaz, as well as the other generic birth control pills containing drospirenone (DRSP), may be associated with a higher risk for blood clots than those pills with other progestins, such as levonorgestrel.

As a result of this determination, the labels for Yasmin, YAZ, Safyral, and Beyaz were revised by Bayer and the FDA in April 2012 by adding information about the various medical studies concerning the increased blood clot risks associated with drospirenone-containing birth control pills.

In turn, the drug labels for the generic DRSP birth control pills -- Ocella, Gianvi, Zarah, Loryna, Syeda, and Vestura -- will be revised by their respective responsible drug companies in the near future, as they are required to do by law.

For more details about this April 2012 drospirenone (DRSP) label revision announcement by the FDA, see: "FDA Drug Safety Communication: Updated information about the risk of blood clots in women taking birth control pills containing drospirenone".

In addition, this list of background articles about certain developments leading up to the April 2012 Yasmin / YAZ / Safyral / Beyaz label change may be of interest to those wanting to know more about this rather significant drug labelling revision:

- [Yasmin / Safyral / Beyaz: February 2012 Label Change Non-Specific To These Bayer Birth Control Pills](#)
- [YAZ / Yasmin January 2012 Update: Minutes And Transcripts For FDA Advisory Committees 2011 Meeting Now Available Online (And More)](#)
- [YAZ / Yasmin: December 2011 FDA Advisory Committees Meeting Background Materials Now Available Online](#)
- [Two More Medical Studies Show Increased Risk Of Blood Clots With Use Of YAZ, Yasmin, And Ocella](#)
YAZ / Yasmin / Ocella Update: October 2011 FDA Study Finds Increased Risk Of Blood Clot Side Effects Like DVT, PE, Stroke, And Heart Attack

YAZ / Yasmin / Ocella: FDA Study Suggests An Increased Risk Of Blood Clots That Can Cause Side Effects Like Pulmonary Embolism

Another Rather "Odd" YAZ Label Change By Bayer: March 2011

Is Bayer Warning Or Attacking With Its New YAZ / Yasmin Package Insert, Or Label, In The U.S

March 2010: Bayer Says It Will Update Yasmin Label In Europe To Add Results From Four Medical Studies

Of course, we will continue to monitor both the drug safety and the legal / litigation aspects of this particular set of birth control pills containing drospirenone (DRSP).

P.S. April 2012 YAZ Prescribing Information (PDF) Recent Major Changes: Warnings and Precautions, Thromboembolic Disorders (5.1) 4/2012

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, Drug Injury Watch – with live links and readers’ Comments.

http://www.DrugInjuryWatch.com