

[Another Rather "Odd" YAZ Label Change By Bayer: March 2011](#)

Provides New Warnings About Certain Side Effects As Regards ALL Birth Control Pills (Not Specific To YAZ)

(Posted by Tom Lamb at www.DrugInjuryWatch.com on March 21, 2011; see <http://bit.ly/gLgf06>)

The bottom line is this: There is nothing specific about YAZ in the new warning language added to the YAZ label by Bayer in March 2011. Instead, these new warnings pertain to ALL combined oral contraceptives (COCs), or birth control pills.

Moreover, one expects a similar "odd" label change will be done for the several other Bayer birth control pills which contain drospirenone (DRSP) and ethinyl estradiol (EE), namely Yasmin, Safyral, and Beyaz -- while, again, stating nothing that is specific to each.

And, thereafter, we will likely see: (1) Teva Pharmaceuticals and Barr Laboratories make an identical label change for Ocella, a generic version of Yasmin, as well as Gianvi, a generic version of YAZ; and, (2) Watson Pharmaceuticals do likewise for Zarah, another generic version of Yasmin.

So what did the March 2011 YAZ label change add to the current side effects warnings as regards this popular birth control pill? As regards YAZ in particular, not much it seems.

A [March 11, 2011 Supplemental Approval letter from the FDA to Bayer HealthCare Pharmaceuticals](#) told the drug company that it can change the labeling for YAZ as follows:

This "Prior Approval" supplemental new drug application provides for the inclusion of new information regarding the increased risk of venous thromboembolic events (VTE) in women using combined oral contraceptives (COCs) in **WARNINGS AND PRECAUTIONS**, subsection **Thromboembolic Disorders and Other Vascular Problems**. The new information specifically concerns the temporal trend in the increased risk relative to starting a COC and alterations in the risk following temporary discontinuation and then resumption of a COC....

In addition, this supplement (1) modifies the subsection **Carbohydrate and Lipid Metabolic Effects** in **WARNINGS AND PRECAUTIONS**...

As such, the [revised YAZ package insert, or label, approved by the FDA in March 2011](#) now includes this new language in its **WARNINGS AND PRECAUTIONS** section:

5.1 Thromboembolic Disorders and Other Vascular Problems

... The use of COCs increases the risk of venous thromboembolism. However, pregnancy increases the risk of venous thromboembolism as much or more than the use of COCs. The risk of venous thromboembolism in women using COCs has been estimated to be 3 to 9 per 10,000 woman-years. The risk of VTE is highest during the first year of use. Interim data from a large, prospective cohort safety study of various COCs suggest that this increased risk, as compared to that in non-COC users, is greatest during the first 6 months of COC use. Interim data from this safety study indicate that the greatest risk of VTE is present after initially starting a COC or restarting (following a 4 week or greater pill-free interval) the same or a different COC.

5.7 Carbohydrate and Lipid Metabolic Effects

... Women with hypertriglyceridemia, or a family history thereof, may be at an increased risk of pancreatitis when using COCs.

From our perspective, this is the second rather "odd" YAZ label revision by Bayer in the past year.

As we reported previously, back in April 2010 Bayer HealthCare Pharmaceuticals announced that that it was updating the labels for YAZ® (3 mg drospirenone / 0.02 mg ethinyl estradiol) and Yasmin® (3 mg drospirenone / 0.03 mg ethinyl estradiol) in the United States. The title for an earlier article about that April 2010 label change -- "[Is Bayer Warning Or Attacking With Its New YAZ / Yasmin Package Insert, Or Label, In The U.S.](#)"-- hints at our impression of this previous YAZ label change by Bayer.

It seems to us that neither the April 2010 label change nor this new March 2011 revision to the YAZ package insert adds much in terms of providing any real warning for women who are using YAZ.

What do you think?

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>