# Ortho Evra "Black-Box" Warning About Risks Of Blood Clots Added To Package Insert In March 2011

## Warnings Increased About Risk Of Side Effects Like Pulmonary Embolism (PE) And Deep Vein Thrombosis (DVT)

(Posted by Tom Lamb at www.DrugInjuryWatch.com on April 16 , 2011; see http://bit.ly/fJoonJ)

In March 2011 Ortho-McNeil-Janssen Pharmaceuticals, Inc. revised the Prescribing Information (more commonly called the "package insert" or "label") for its Ortho Evra (norelgestromin/ ethinyl estradiol) transdermal system to give a stronger warning about blood clot related side effects like pulmonary embolism (PE) and deep vein thrombosis (DVT).

Previously, the Boxed Warning, or "Black-Box" Warning, for the Ortho Evra skin patch birth control product only included a short paragraph titled "Cigarette Smoking and Serious Cardiovascular Risks".

Now the March 2011 version of the Ortho Evra label has a Black Box warning which includes these two new paragraphs about a woman's risk of suffering adverse events while using the Ortho Evra patch:

> **Risk of Venous Thromboembolism**
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> The risk of venous thromboembolism (VTE) among women aged 15-44 who used the ORTHO EVRA® patch compared to women who used oral contraceptives containing 30-35 mcg of ethinyl estradiol (EE) and either levonorgestrel or norgestimate was assessed in four U.S. case-control studies using electronic healthcare claims data. The odds ratios ranged from 1.2 to 2.2; one of the studies found a statistically significant increased risk of VTE for current users of ORTHO EVRA® (*see **WARNINGS - Table 5***).
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> **Pharmacokinetic Profile of Ethinyl Estradiol**
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> The pharmacokinetic (PK) profile for the ORTHO EVRA® patch is different from the PK profile for oral contraceptives in that it has higher steady state concentrations and lower peak concentrations. Area under the time-concentration curve (AUC) and average concentration at steady state for ethinyl estradiol (EE) are approximately 60% higher in women using ORTHO EVRA® compared with women using an oral contraceptive containing 35 mcg of EE. In contrast, peak concentrations for EE are approximately 25% lower in women using ORTHO EVRA®. It is not known whether there are changes in the risk of serious adverse events based on the differences in PK profiles of EE in women using ORTHO EVRA® compared with women using oral contraceptives containing 30-35 mcg of EE. Increased estrogen exposure may increase the risk of adverse events, including venous thromboembolism. (*See **WARNINGS** and **CLINICAL PHARMACOLOGY**, Transdermal versus Oral Contraceptives*.)

Our March 2010 article about the safety profile of Ortho Evra, "Recent Report About Ortho Evra Safety Seems To Contradict Earlier Findings From Same Group", covered some of the developments which led to an April 2010 Ortho Evra label change.

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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