



FDA News

FOR IMMEDIATE RELEASE

January 18, 2008

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FDA Approves Update to Label on Birth Control Patch

The U.S. Food and Drug Administration (FDA) today approved additional changes to the Ortho Evra Contraceptive Transdermal (Skin) Patch label to include the results of a new epidemiology study that found that users of the birth control patch were at higher risk of developing serious blood clots, also known as venous thromboembolism (VTE), than women using birth control pills. VTE can lead to pulmonary embolism.

The label changes are based on a study conducted by the Boston Collaborative Drug Surveillance Program (BCDSP) on behalf of Johnson and Johnson. The patch was studied in women aged 15-44. These recent findings support an earlier study that also said women in this group were at higher risk for VTE.

"For women that choose to use contraceptives, it is important that they thoroughly discuss with their health care providers the risks and benefits involved," said Janet Woodcock, M.D., the FDA's deputy commissioner for scientific and medical programs, chief medical officer, and acting director of the Center for Drug Evaluation and Research.

"This is an example of FDA working in tandem with the drug manufacturer to keep the public informed of new safety data and epidemiological studies that may impact health decisions about the use of FDA approved products."

In September 2006, FDA revised the label for Ortho Evra to warn women of the risk of VTE based on two epidemiology studies. One study, conducted by i3 Ingenix, showed that some women using the patch were at a two-fold greater risk of developing VTE. The other study, conducted by BCDSP, showed they were not at increased risk compared to women using birth control pills containing 30-35 micrograms of estrogen and the progestin norgestimate.

Ortho Evra is a prescription patch that releases ethinyl estradiol (an estrogen hormone) and norelgestromin (a progestin hormone) through the skin into the blood stream. Because the hormones are processed by the body differently than hormones from birth control pills, women using the product will be exposed to about 60 percent more estrogen than if they were using typical birth control pills containing 35 micrograms of estrogen. Increased levels of estrogen may increase the risk of side effects, including VTE. Women should discuss with their health care provider the possible increased risk of VTE with Ortho Evra, which is applied once a week, and balance this risk against the increased chance of pregnancy if women do not take their birth control pill daily.

The FDA believes that Ortho Evra is a safe and effective method of contraception when used according to the labeling, which

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recommends that women with concerns or risk factors for serious blood clots talk with their health care provider about using Ortho Evra versus other contraceptive options.

The Ortho Evra Contraceptive Transdermal Patch is manufactured by Ortho McNeil Pharmaceuticals, a division of Johnson and Johnson.

Consumers with questions regarding this drug or any medications may contact FDA's Division of Drug Information at: 888-INFO-FDA (888-463-6332), or email to: druginfo@fda.hhs.gov.

To view additional information on the use of Ortho Evra please visit: www.fda.gov/cder/drug/infopage/orthoevra/default.htm

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