

## News & Events

This is a revised version of this press release, originally issued Nov. 10, 2005. The 5th paragraph has been replaced.

### FDA NEWS RELEASE

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### FDA Updates Labeling for Ortho Evra Contraceptive Patch

The Food and Drug Administration today approved updated labeling for the Ortho Evra contraceptive patch to warn healthcare providers and patients that this product exposes women to higher levels of estrogen than most birth control pills. Ortho Evra was the first skin patch approved for birth control.

It is a weekly prescription patch that releases ethinyl estradiol (an estrogen hormone) and norelgestromin (a progestin hormone) through the skin into the blood stream. FDA advises women to talk to their doctor or healthcare provider about whether the patch is the right method of birth control for them.

Furthermore, women taking or considering using this product should work with their health care providers to balance the potential risks related to increased estrogen exposure against the risk of pregnancy if they do not follow the daily regimen associated with typical birth control pills. Because Ortho Evra is a patch that is changed once a week, it decreases the chance associated with typical birth control pills that a woman might miss one or more daily doses.

The addition of this new warning is a result of FDA's and the manufacturer's analysis directly comparing the levels for estrogen and progestin hormones in users of Ortho Evra with those in a typical birth control pill. In general, increased estrogen exposure may increase the risk of blood clots. However, it is not known whether women using Ortho Evra are at a greater risk of experiencing these serious adverse events.

The new bolded warning specifically states that women who use Ortho Evra are exposed to about 60 percent more total estrogen in their blood than if they were taking a typical birth control pill containing 35 micrograms of estrogen. However, the maximal blood level of estrogen (peak blood levels) is about 25% lower with Ortho Evra than with typical birth control pills. While the estrogen level with the patch remains constant for one week until the patch is removed, the peak blood

levels with a daily birth control pill rapidly declines to levels that are lower than on the Ortho Evra.

FDA is continuing to monitor safety reports for the Ortho Evra patch. The manufacturer, Ortho McNeil Pharmaceuticals is conducting additional studies to compare the risk of developing serious blood clots in women using Ortho Evra to the risk in women using typical birth control pills that contain 35 micrograms of estrogen.

The new labeling information is available along with additional information for healthcare providers and consumers online at:  
[www.fda.gov/cder/drug/infopage/orthoevra/default.htm](http://www.fda.gov/cder/drug/infopage/orthoevra/default.htm).

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