

Drugs

Ortho Evra Questions and Answers (9/20/2006)

For current questions and answers on Ortho Evra, please see

[Ortho Evra \(norelgestromin/ethinyl estradiol\) Information](#)

1. What is FDA announcing today, September 20, 2006?

FDA is announcing an update to the Ortho Evra label with the results of two separate epidemiology studies sponsored by Johnson and Johnson that were designed to evaluate the risk of experiencing serious side effects (especially due to venous and arterial blood clots) when using Ortho Evra.

2. Is this information new?

Some of the information that is being added to the Ortho Evra label was previously reported by Johnson and Johnson on February 16, 2006 in a press release. Information in that press release was based, in part, on an *interim report* from one of the two epidemiological studies. The label is now being updated with the available results from the two studies.

3. Why were these epidemiology studies done?

These two epidemiology studies were conducted to evaluate the risk of developing a serious blood clot in women using Ortho Evra compared to women using a different, commonly prescribed, oral contraceptive. Concern about this risk was originally based on reports of serious blood clots to FDA and to the sponsor that suggested that Ortho Evra may have a greater risk for venous thromboembolism (VTE), at least in some women, compared to oral contraceptives.

4. What information was found in the two studies?

Both studies were conducted using electronic health care claims data. However, the results of the two studies are different.

The first study was conducted by the Boston Collaborative Drug Surveillance Program. This study found that the risk of non-fatal VTE events associated with the use of the Ortho Evra contraceptive patch is similar to the risk associated with the use of oral contraceptive pills (OCs) containing 35 micrograms of ethinyl estradiol (an estrogen) and norgestimate (a progestin

hormone).

The second study, which also included patient chart review, was conducted by another group of investigators (i3 Ingenix). Results of this second case-control study show an approximate 2-fold increase in the risk of medically verified VTE events in users of Ortho Evra compared to users of norgestimate-containing oral contraceptives containing 35 micrograms of estrogen. Longer follow-up for VTE, heart attack and stroke, has been requested by FDA.

5. What does this new information mean to women who are using or considering using Ortho Evra?

Even though the results of the two studies are conflicting, the results of the second epidemiology study support FDA's concerns regarding the potential for Ortho Evra use to increase the risk of blood clots in some women. The label has recommended and continues to recommend that women with concerns or risk factors for thromboembolic disease talk with their healthcare provider about using Ortho Evra versus other contraceptive options.

6. If a woman wants to change from the Ortho Evra patch to a birth control pill, what should she do?

Talk to her health care professional. The health care professional will help her make this change.

7. What other actions has the FDA taken with regard to Ortho Evra?

In November 2005, the FDA added information to the Ortho Evra label about the increased exposure to estrogen seen in women who use Ortho Evra compared with oral contraceptives containing norgestimate and 35 micrograms of ethinyl estradiol based on the results of pharmacokinetic studies.

8. Where can I find more information on this?

If you have further questions regarding any medications, please contact the Center for Drug's Division of Drug Information at: 888-INFO-FDA (888-463-6332), or email us at: druginfo@fda.hhs.gov.

To view additional information on the use of Ortho Evra please visit our website at: [Ortho Evra \(norelgestromin/ethinyl estradiol\) Information](#)