



***Student Health and Counseling Services***

*California State University San Marcos  
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November 14, 2005

Dear Patient,

Our records show that you have been given a prescription for a hormone contraceptive method known as ORTHO EVRA® or “the Patch.” On November 10, 2005, the Food and Drug Administration (FDA) added a warning to the labeling of ORTHO EVRA® transdermal contraceptive. 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. This analysis showed that women who use ORTHO EVRA® are exposed to about 60% more estrogen than if they were to use a typical birth control pill containing 35 micrograms of estrogen. In general, increased estrogen exposure raises the risk of developing blood clots and some other side effects. However, it is not known for certain whether women using ORTHO EVRA® are at a greater risk of experiencing serious adverse events than those who are taking a birth control pill containing 35 micrograms or less of estrogen. There is strong evidence that cigarette smoking increases the risk of serious cardiovascular side effects, especially if you are over 35. Women who use the Patch are strongly advised not to smoke. Some women should not use the Patch, including women who have blood clots, certain cancers, a history of heart attack or stroke, as well as those who are or may be pregnant. Women who have ever had migraine headaches with an aura should also not use the patch.

You may have seen information regarding legal actions being taken against the manufacturer of ORTHO EVRA® because some women using this product have had blood clots in their legs, lungs, heart or brain. According to information gathered from federal death and injury reports by the Associated Press earlier this year, about a dozen women, most in their late teens and early 20s, died in 2004 from blood clots believed to be related to the birth-control patch, and dozens more survived strokes and other clot-related problems. However, more than 4 million women have used ORTHO EVRA® since it went on sale in 2002, so the chance of serious risk seems to be fairly small.

At this time, the FDA is not suggesting that women using ORTHO EVRA® change to another contraceptive method. However, we thought that you should know the latest information. If you have concerns, please talk to your Student Health Services physician or nurse practitioner about how this information relates to your future use of ORTHO EVRA®. If you would like to switch because of the question of increased risk, please make an appointment ASAP by calling (760) 750-4915.

Sincerely,

Karen Nicholson, MD, M.P.H.  
Director

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