



PIC QUESTION OF THE WEEK: 1/19/09

Q: Can venlafaxine extended release tablets be dispensed by a pharmacist as an alternative to Effexor XR capsules?

A: Effexor XR (venlafaxine extended release *capsules*) is one of the most commonly prescribed antidepressant medications in this country and is ranked 23rd in the number of new and refill prescriptions dispensed by pharmacists in 2007. In addition to its value for treating depression, the drug is also beneficial for the management of anxiety. The Food and Drug Administration (FDA) has recently approved venlafaxine extended release *tablets* manufactured by Osmotica Pharmaceuticals. Availability of this new dosage form has created a great deal of confusion among practicing pharmacists. Most of the uncertainty is based on the question of whether the products can be substituted for one another. Each of these formulations of venlafaxine is available in 37.5 mg, 75 mg, and 150 mg strengths. The extended release *tablets* are also available in a 225 mg strength. The FDA "Orange Book" provides an extensive list of drugs and dosage forms that can be substituted for one another. The rating system is based on a number of factors and criteria. A therapeutic equivalency rating of *AB* indicates that the products "contain the same active ingredient(s), are of the same dosage form, route of administration, and are identical in strength or concentration." Drugs rated as *AB* can be substituted for one another. Neither Effexor XR nor venlafaxine extended release tablets has received an equivalency rating from the FDA, thus, they cannot be substituted for one another. Though the products contain the same amount of active drug, they are not identical dosage forms. Venlafaxine extended release tablets are, however, now considered the reference listed drug (RLD) for this dosage form by the FDA. Prescribers must specifically write for venlafaxine extended release tablets in order for that product to be dispensed. The current patent on Effexor XR capsules is valid through 2017. Patients using this product should be aware that a portion of or the entire tablet matrix may appear in the stool, however, the active ingredient has been effectively absorbed.

References:

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