Medications in Pregnancy

According to information published by the Centers for Disease Control and Prevention’s National Center on Birth Defects and Developmental Disabilities (CDC NCBDDDD), the use of four or more medications has tripled and use of prescription medications has increased over 60% over the past three decades. Under the Federal Food, Drug, and Cosmetic Act, the FDA has responsibility for ensuring that prescription drug and biological products are accompanied by labeling that summarizes scientific information concerning their safe and effective use. The FDA is also responsible for regulations on labeling for use during pregnancy, during labor and delivery, and by nursing mothers.

The current regulations provide that, unless a drug is not absorbed systematically and is not known to have a potential for indirect harm to a fetus, a “Pregnancy” subsection must be included within the “Use in Special Populations” section of the labeling. The FDA regulations require that each product be classified under one of five pregnancy categories (A, B, C, D, or X) on the basis of risk of reproductive and developmental adverse effects or, for certain categories, on the basis of such risk weighed against potential benefits. The following is a synopsis of the FDA fetal risk categories:

- Pregnancy Category A = Adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of a risk in later trimesters)
- Pregnancy Category B = Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women
- Pregnancy Category C = Animal reproduction studies have shown an adverse effect on the fetus, and there are no adequate and well-controlled studies in humans, and the
benefits from the use of the drug in pregnant women may be acceptable despite its potential risks

- Pregnancy Category D = There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks

- Pregnancy Category X – Studies in animals or humans have demonstrated fetal abnormalities or there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit

For more information on FDA labeling for use during pregnancy, during labor and delivery, and by nursing mothers, please see http://www.gpo.gov/fdsys/pkg/FR-2008-05-29/pdf/E8-11806.pdf

For further information regarding substance use/abuse in women during pregnancy, please contact Karen Kuehn Howell, Ph.D., at the Center for Maternal Substance Abuse and Child Development, Emory University School of Medicine, Department of Psychiatry and Behavioral Sciences, 12 Executive Park Drive NE, Atlanta, Georgia, 30329. You can also phone us at 404-712-9829 or visit our website at http://www.emory.edu/MSACD

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