



MEDICATIONS AND PREGNANCY

ARE OVER-THE-COUNTER (OTC) DRUGS DANGEROUS DURING PREGNANCY?

According to the New England Journal of Medicine, an estimated 10 to 45 percent of pregnant women in the first trimester, unaware of their condition, reach for the most common OTC drug, aspirin. Aspirin and other drugs containing salicylate are not recommended throughout pregnancy, especially during the last 3 months, except under a doctor's supervision. Acetylsalicylate, a common ingredient in many OTC painkillers, may prolong pregnancy and cause excessive bleeding before and after delivery.

Overall, according to Debbie Limkins of FDA's division of OTC drug evaluation, most other OTC drugs can be used during pregnancy with the supervision of a physician. Although scientists do not know the effects on the fetus of all OTC and prescriptions drugs, some are known to cause birth defects and should be avoided.

Since 1984, all OTC drug products have carried the following warning: "As with any other drug, if you are pregnant or nursing, seek the advice of a health professional before using this product." In July 1990, FDA issued a regulation requiring all oral and rectal nonprescription aspirin and drugs that contain aspirin to include the additional warning "It is especially important not to use aspirin during the last 3 months of pregnancy unless specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery."

One drug that can cause severe birth defects is Accutane, or isotretinoin. Accutane, a derivative of vitamin A, is a powerful prescription drug that can clear severe cystic acne, but can cause birth defects (such as heart defects, small jaw, cleft palate, and skull and facial disfigurements) in about 1 out of every 4 exposed fetuses. Accutane can also cause miscarriages.

Since its approval, Accutane has been labeled as being in pregnancy category X, meaning it should not be used during pregnancy. However, due to persistent reports of birth defects associated with the use of the drug in 1988, the manufacturer, Hoffman-La Roche, began including additional patient information in the packaging, including a drawing of a baby with birth defects associated with the drug. Before being permitted to take Accutane, a woman of childbearing age must sign a consent form stating that she has been fully informed of the drug's side effects.

Another derivative of vitamin A, etretinate (or Tegison), was approved in the mid-1980's to treat psoriasis. This drug is also forbidden for use by women who are pregnant or who are likely to become pregnant either while taking it or for a certain period after they have stopped taking it.

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