THINKING ABOUT BECOMING PREGNANT?

If you are pregnant or thinking about becoming pregnant, talk with your Healthcare provider about any medications you are taking or thinking about taking. This includes prescription and over-the-counter medications, as well as dietary or herbal products.

Why is being ready for pregnancy so important?
Conception occurs about 2 weeks before your period is due. That means you may not even know you're pregnant until you're more than 3 weeks pregnant. Yet your baby is most sensitive to harm 2 to 8 weeks after conception. This is when your baby's organs (such as the heart) begin to form. Anything you eat, drink, smoke or are exposed to can affect your baby. That's why it's best to start acting as if you're pregnant before you actually are.

When should I talk with my Healthcare Provider about pregnancy?
You can talk with your Healthcare Provider about pregnancy at any time, even before you're thinking about getting pregnant. You can talk about your diet, habits, lifestyle and any concerns you have. Plan on visiting your Healthcare Provider within a year before you want to get pregnant.

Talk to Your Healthcare Provider:

Pregnant women should not stop or start taking any type of medication that they need without first talking with their Healthcare Provider. Women who are planning to become pregnant should discuss the need for any medication with their Healthcare Provider **before becoming pregnant** and ensure they are taking only medications that are necessary.

Effects of Medications during Pregnancy

Before becoming pregnant talk to your Healthcare Provider!!

Some psychiatric medications should not be taken during the first trimester such as Lithium. Depakote is generally considered unsafe during pregnancy. Please see the attached list of psychiatric medications and concerns related to pregnancy and breastfeeding.

We know little about the effects of taking most medications during pregnancy. This is because pregnant women are often not included in studies to determine safety of new medications before they come on the market. Less than 10% of medications approved by the U.S. Food and Drug Administration (FDA) since 1980 have enough information to determine their risk for birth defects.

Because of studies conducted after medications come on the market, we do know that taking certain medications during pregnancy can cause serious birth defects. Examples are thalidomide (also known as Thalamid®) and isotretinoin (also known as Accutane®). Such medications should be avoided by all women who are or might become pregnant.

For women who are taking these medications, it is important to discuss effective contraception methods with their doctor. While some medications are known to be harmful when taken during pregnancy, we don't know the safety or risk of most medications.

The effects depend on many factors, such as:

How much medication is taken (sometimes called the *dose*).

When during the pregnancy the medication is taken.

Other health conditions a woman might have.

Other medications a woman takes.

The important thing to remember is to talk to your Healthcare Provider. Be sure to tell your Healthcare Provider about all medications and herbal or dietary supplements you're taking or planning to take, so you can make sure you're taking only what is necessary.

Lists of Safe Medications during Pregnancy

Many Internet websites post lists of medications that are safe to take during pregnancy. But for many of the medications listed, there is not enough known to determine their safety or risk for use during pregnancy.

Donôt make decisions about medication use during pregnancy based on lists you find online. Instead use the lists as a starting point to talk with your **Healthcare Provider**.

Donôt stop or start taking any type of medication that you need without first talking with a **Healthcare Provider**.

A conversation with a **Healthcare Provider** can help ensure that you are taking only what is necessary.

Discussing Current Medications

Some pregnant women must take medications to treat health conditions. For example, if a woman has asthma, epilepsy (seizures), high blood pressure, or depression, she might need to continue to take medication to stay healthy during pregnancy. If these conditions are not treated, a pregnant woman or her unborn baby could be harmed. It is important for a woman to discuss with her **Healthcare Provider** which medications are needed during pregnancy. She also should talk to her **Healthcare Provider** about which medications are likely to be the safest to take during pregnancy. It is important to balance the possible risks and benefits of any medication being considered. Suddenly stopping the use of a medication may be riskier than continuing to use the medication while under a **Healthcare Providerôs** care. It also is important to know that dietary and herbal products, such as vitamins or herbs added to foods and drink, could be harmful to an unborn baby. These products can have other side effects when used during pregnancy. Itôs best for a woman to talk with her **Healthcare Provider** about everything sheôs taking or thinking about taking.

Accidental Exposure

Sometimes women take medication before they realize that they are pregnant. When this happens, they may worry about the effects of the medication on their unborn baby. The first thing a woman who is pregnant or who is planning on becoming pregnant should do is talk with her **Healthcare Provider**. Some medications are harmful when taken during pregnancy, but others are unlikely to cause harm.

FDA Pregnancy Categories

The FDA has established five categories to indicate the potential of a drug to cause birth defects if used during pregnancy. The categories are determined by the reliability of documentation and the risk to benefit ratio. They do not take into account any risks from pharmaceutical agents or their metabolites in breast milk. The pregnancy categories are:

Category A

Adequate and well-controlled studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters).

Example drugs or substances: **levothyroxine**, **folic acid**, **magnesium sulfate**, **liothyronine**

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.

Example drugs: **metformin**, **hydrochlorothiazide**, **cyclobenzaprine**, **amoxicillin**, **pantoprazole**

Category C

Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Example drugs: **tramadol**, **gabapentin**, **amlodipine**, **trazodone**, **prednisone**

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 potential benefits may warrant use of the drug in pregnant women despite potential risks.

Example drugs: **lisinopril**, **alprazolam**, **losartan**, **clonazepam**, **lorazepam**

Category X

Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits.

Example drugs: **atorvastatin**, **simvastatin**, **warfarin**, **methotrexate**, **finasteride**

Category N

FDA has not classified the drug.

Example drugs: **aspirin**, **oxycodone**, **hydroxyzine**, **acetaminophen**, **diazepam**

Pregnancy and Post-Partum Psychopharm Guidelines

General Principles:

- Treatment involves weighing the risks of the illness vs. the risk of medication.
- There are no "safe" medications—all involve some degree of risk.
- Typically we have a higher threshold for using medications during pregnancy.
- Informed consent is key and if possible involve the partner.
- Abrupt discontinuation may lead to earlier relapse or withdrawal symptoms.
- Most of the toxicity to the fetus occurs during the first trimester but craniofacial anomalies and neurobehavioral effects can occur later in pregnancy.
- Toxicities to the fetus include: (1) Major malformations (base rate is 3%), (2) Minor malformations, (3) adverse pregnancy outcomes (e.g., miscarriage), (4) Neonatal toxicity (e.g., withdrawal) and (5) Neurobehavioral effects.
- Good reference: Micromedex REPROTOX®

Antidepressants (SSRIs, SNRIs, Remeron, Wellbutrin):

- Considered reasonably safe during pregnancy.
- The exception is Paxil.
- Risks vs. Benefits:
    - Risks of not taking medication: (1) Relapse risk, (2) Poor prenatal care, (3) Increased post-partum depression, (4) Poor bonding/attachment, (5) Greater risk of depression in children.
    - Risks of taking medication: (1) Heart defects (Paxil), (2) Miscarriage, (3) Shorter Gestation (by approx 1 week), (4) Primary Pulmonary Hypertension of the Newborn (PPHN, increased risk 6X from 1-2:1000 to 6-12:1000), (5) Neonatal toxicity/withdrawal, (6) All pass into breast milk to some degree (Zoloft the least).

Antianxiety and Sleep (hypnotic) medications:

- **Benzodiazapines** (e.g., Ativan)—Concerns about withdrawal after birth and long-term neurobehavioral problems.
- **Vistaril**—Safest of the antianxiety drugs (except Buspar) and also helpful for sleep.
- **Ambien**—Used a great deal but long terms toxicities unknown.

Mood Stabilizers:

- **Lithium**.
    - Increased risk of cardiac malformation during first trimester.
    - Generally consider fairly safe after the first trimester (and would be first choice of mood stabilizers at this time).
    - Not safe for breastfeeding.
- **Depakote**
    - Generally considered unsafe during pregnancy because of major and minor malformations, craniofacial anomalies and neurobehavioral effects.
    - Passes into breast milk.
- **Lamictal—**Somewhat increased risk of abnormalities but definitely safer than Depakote.

Antipsychotics/Mood Stabilizers:

- **Haldol**: The first choice both during pregnancy and breastfeeding (usually discouraged).
- **Atypical antipsychotics**: Not a lot known about long-term safety. Second choice. Typically avoid in breastfeeding.

FDA Pregnancy Drug Risk Categories: **A**: Controlled studies in women fail to demonstrate a risk to the fetus in the first trimester (and there is no evidence of a risk in later trimesters), and the possibility of fetal harm appears remote. **B**: Either animal-reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women, or animal-reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester (and there is no evidence of a risk in later trimesters). **C**: Either studies in animals have revealed adverse effects on the fetus (teratogenic or embryocidal or other) and there are no controlled studies in women, or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus. **D**: There is positive evidence of human fetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective). **X**: Studies in animals or human beings have demonstrated fetal abnormalities, or there is evidence of fetal risk based on human experience or both, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.

David A Harrison, MD, PhD. University of Washington 2008 V1.0 Nov 2008