Breastfeeding Safety: Stimulants
INFORMATION BULLETIN

This information is intended to supplement your health care provider's advice.
It should not take the place of medical care or advice from your health care provider.

The reference book by Thomas Hale, *Medications and Mothers' Milk*, has emerged as the standard resource for rating breastfeeding safety. In this entry, we provide a summary of Hale's breastfeeding safety ratings and recommendations for **Stimulants**. Hale includes a 5-category system of ***Lactation Risk Categories,*** which include:

- **L1 SAFEST** – Drug has been taken by many breastfeeding women without evidence of adverse effects in nursing infants OR controlled studies have failed to show evidence of risk.
- **L2 SAFER** – Drug has been studied in a limited number of breastfeeding women without evidence of adverse effects in nursing infants.
- **L3 MODERATELY SAFE** – Studies in breastfeeding have shown evidence for mild non-threatening adverse effects OR there are no studies in breastfeeding for a drug with possible adverse effects.
- **L4 POSSIBLY HAZARDOUS** – Studies have shown evidence for risk to a nursing infant, but in some circumstances the drug may be used during breastfeeding.
- **L5 CONTRAINDICATED** – Studies have shown significant risk to nursing infants. The drug should NOT be used during breastfeeding.

Another risk estimate is provided by quantifying a nursing infant's level of exposure. Hale reports the ***Relative Infant Dose (RID)*** as an index of the level of exposure. Expressed as a percentage, the RID is calculated by dividing the infant's total daily ingestion of a medicine via nursing (mg per kg infant body weight) by the mother's daily dose of the medicine (mg per kg maternal body weight). Hale advises that "a Relative Infant Dose of <10% is considered safe", though we would caution that this is a general observation that has never been objectively verified. Earlier studies had utilized milk:plasma ratio as an index of the level of exposure, but milk:plasma ratios because they do not provide an estimate of the total amount of a drug that is transferred to a nursing baby.

General Suggestions

- **Mother's Side Effects Predict Baby's Safety Concerns** – This intuitive observation helps direct the focus of your concern. For example, if a medicine is likely to cause sedation in adults, then observe your nursing infant for sedation. If it causes loss of appetite in adults, then carefully monitor your infants' growth.
- **Laboratory Monitoring for Mother Should Also Be Performed for Baby** – Some medicines require laboratory safety monitoring. For example, liver tests are monitored in women taking valproate, blood counts in women taking clozapine, and kidney tests in women taking lithium. If you are breastfeeding while taking a medicine that requires laboratory monitoring, ask for these laboratory tests for your baby as well.
- **Pregnancy Exposure Is Much Higher Than Breastfeeding Exposure** – Fetal exposure levels to a medicine are usually much higher than exposure via nursing. Thus, if your child was exposed to a medicine during pregnancy, then nursing simply continues exposure to that same medicine at a much lower level.
- **Long-Term Effects of Breastfeeding Exposure Are Not Well-Studied** – Breastfeeding safety ratings focus on risks that can be seen when your child is still nursing. However, keep in mind that there may be developmental effects of nursing exposure that will not be evident until much later.
- **Pumping and Dumping Can Reduce Exposure Levels to Occasional Medicines** – Peak breast milk levels of a medicine occur within the first hours after a dose. If taking an "as needed" dose of a medicine, you can reduce your baby's exposure by: 1) maintaining a supply of pumped/stored breast milk; 2) take the medicine immediately AFTER nursing; 3) use stored breast milk (or formula) at your baby's next feeding; 4) at this time, pump and discard milk from both breasts; 5) resume regular breastfeeding at the next feeding.

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Lactation Category	Generic Name	Brand Name(s)	Class	Relative Infant Dose
L2 - SAFER				
L2	None			
L3 – MODERATELY SAFE				
L3	Clonidine[1]	Catapres	Non-stimulant	0.9% - 7.1%
L3	Dexmethylphenidate	Focalin	Stimulant	Not reported
L3	Dextroamphetamine[2]	Dexedrine, Dextrostat	Stimulant	1.8% - 6.9%
L3	Guanfacine[1]	Intuniv, Tenex	Non-stimulant	Not reported
L3	Lisdexamfetamine	Vyvanse	Stimulant	1.8% - 6.2%
L3	Methylphenidate	Concerta, Daytrana, Metadate, Ritalin	Stimulant	0.2% - 0.4%
L3	Mixed amphetamine[2,3]	Adderall	Stimulant	1.8% - 6.9%
L4 – POSSIBLY HAZARDOUS				
L4	Armodafinil[4]	Nuvigil	Stimulant	Not reported
L4	Atomoxetine	Straterra	Non-stimulant	Not reported
L4	Modafinil[4]	Provigil	Stimulant	Not reported
L5 - CONTRAINDICATED				
L5	Dextroamphetamine[2]	Dexedrine, Dextrostat	Stimulant	1.8% - 6.9%
L5	Mixed amphetamine[2,3]	Adderall	Stimulant	1.8% - 6.9%
L5	Methamphetamine	Desoxyn	Stimulant	Not reported

*[1]Clonidine and guanfacine have been used for decades to manage hypertension. They have also been used to manage ADD/ADHD. [2]Dextroamphetamine and mixed amphetamine salts are rated **L3** by Hale when used as prescribed; however, he assigns an **L5** rating to illicit use of these medications. [3]Mixed amphetamine salts are included in Hale's dextroamphetamine report. [4]Modafinil and Armodafinil (Nuvigil) are stimulants used to treat narcolepsy. They do not have FDA indications for the treatment of ADD.*

Medication Specific Suggestions

- **Clonidine, Guanfacine & Blood Pressure** – Because they are antihypertensives, clonidine and guanfacine may lower blood pressure in nursing infants. Nursing infants exposed to clonidine and guanfacine should be monitored for low blood pressure, sedation, and weakness.
- **Stimulant Monitoring** – Nursing infants exposed to stimulants should be monitored for insomnia, poor appetite, weight loss, and irritability; however, none of the existing studies have reported these complications.
- **Stimulants, Clonidine & Milk Production** – All stimulants increase dopamine activity. Clonidine does as well. In addition to its effects as a neurotransmitter, dopamine also acts as a hormone to lower levels of another hormone, prolactin. As a result, stimulants may lower prolactin levels and thereby reduce breast milk production.
- **Atomoxetine Metabolism** – Approximately 1 of every 14 people is a genetically-determined poor metabolizer of atomoxetine. The half-life of atomoxetine may be over 4 times longer among poor metabolizers. As a result, plasma levels of atomoxetine in nursing infants who are poor metabolizers may be much higher than anticipated.

References: Hale TW. Medications and Mother's Milk: A Manual of Lactational Pharmacology 2012. Amarillo, TX: Hale Publishing, 2012.

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