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Volume 24, Issue No. 3 October, 2007

# Cough and Cold Medications in Pregnancy and Lactation

A survey of pregnant women showed that 62.8% used over-the-counter (OTC) medications at some point during their pregnancy[1]. Pregnant and lactating women may come to a community pharmacy seeking relief for their cold symptoms. Pharmacists need to be able to provide a pregnant or lactating woman with accurate information, if available, regarding use of OTC cough and cold products so that a woman may make an informed decision about whether or not to take a particular product. Pregnant and lactating women should be advised to first try non-pharmacological treatments such as increased hydration, saline nasal spray, a humidifier, and hard candy[2].

In general, it is best to avoid drug therapy during pregnancy, especially during the first trimester. It is recommended to avoid extended release or long-acting formulations, and products that contain alcohol.[2] In addition, it is a good idea to choose a cough and cold product with only one drug, or one that contains the least number of drugs possible. One must also keep in mind that no drug is 100% safe for use in pregnancy, and the risks to the fetus vs. benefits of using the drug must always be carefully weighed.

Breast milk is the most complete nutrition an infant can receive, and provides many health benefits both short and long term. Ideally a mother should avoid using any medications while she is breastfeeding; however this is not always feasible. As with drug use in pregnancy, no drug can be guaranteed 100% safe to use while breastfeeding and one must always weigh the risks to the infant vs. benefits of using the drug. Most drugs are likely safe in breastfeeding mothers, and the risk to the infant of not breastfeeding and instead using infant formula is usually much higher than the risk of exposure to drugs.[3] The age and health of the infant must also be taken into account; use medications cautiously in premature and/or unstable infants. Older, more stable infants can metabolize and clear medications more easily.[3] Drugs used directly in infants are generally considered to pose less risk.

The following is a discussion of commonly used OTC cough and cold drugs. The discussion assumes all non-pharmacologic options have been explored prior to resorting to pharmacologic therapies.

## Decongestants

Pregnancy

Data is suggestive of a possible correlation between use of vasoconstrictors during first trimester and the development of gastroschisis (congenital fissure of the ventral abdominal wall) and hemifacial microsomia (underdevelopment of the lower half of one side of the face).[4,5] Both of these anomalies are thought to be due to vascular disruption.[5] However, other anomalies thought to be associated with vascular disruption

have not been attributed to first trimester use of pseudoephedrine and, therefore, maternal illness (fever, virus) needs to be considered as a cause of these anomalies.[3] No other congenital anomalies have been associated with the use of vasoconstrictors in the first trimester.[4,5]

Human data are limited in regards to the effect on uterine blood flow during the third trimester, though single dose studies of pseudoephedrine in women in 3rd trimester found no significant changes to uterine blood flow or fetal blood pressure. Of the systemic decongestants, pseudoephedrine requires the highest dose to affect blood pressure (may be up to four times the therapeutic dose) and, therefore, has been considered the preferred systemic decongestant for use in pregnancy.[4]

Little information is available regarding the topical decongestants oxymetazoline and xylometazoline. Of the available information, no congenital anomalies have been associated with these agents.[4,5] Based on the limited information, infrequent therapeutic doses of oxymetazoline and xylometazoline are not thought to cause problems, though use should be restricted in patients with borderline placental reserve.[3]

Lactation

Adverse effects of systemic decongestants on the nursing infant are unlikely,[2] though irritability has been reported occasionally in association with pseudoephedrine.[6] Concern regarding systemic decongestants is the potential to reduce milk supply in the breastfeeding mother. Single 60mg doses of pseudoephedrine have reduced supply by over 20%; phenylephrine is thought to act similarly, though no data exists.[2,6] Therefore, these drugs need to be used with caution in mothers with poor or marginal milk supply,[2,6] including those whose milk supply has not been established (may take up to six to eight weeks postpartum[2]) and those in late-stage lactation.

No data exist concerning the use of topical decongestants in lactation. However, experts suggest oxymetazoline is unlikely to be harmful to the infant[6,7] and is suggested by some as first line pharmacotherapy.[6]

**Recommendation:**

**In pregnancy, pseudoephedrine, in the lowest dose and shortest duration possible is considered the decongestant of choice. Oxymetazoline and xylometazoline can be considered. During lactation, systemic decongestants are best avoided when breastmilk production is poor or marginal. Oxymetazoline and xylometazoline are considered drugs of choice.**

## Antihistamines

Pregnancy

Human data does not suggest chlorpheniramine is teratogenic.[4,5] Some reports have associated brompheniramine and diphenhydramine with birth defects, though the majority of data has found no association.[4,5] In general, first generation antihistamines are considered safe in pregnancy.[3,4] Based on adequate human data, loratadine has not been shown to increase risks when taken during pregnancy.[3,4,5] While other second generation antihistamines, desloratadine, cetirizine and fexofenadine, are all active metabolites of drugs that have not been implicated as causing harm in pregnancy, there is a paucity of human data with these agents.[3,4,5] Of the second generation antihistamines, loratadine and cetirizine are recommended;[3] loratadine has the most human data.

Lactation

Milk levels of first generation antihistamines are low or unknown.[2,6] Nonetheless, effects such as irritability, excessive crying and sleep disturbances in the infant have been reported[2] and there is a small chance these agents may reduce milk supply.[6] Occasional small doses are not expected to be harmful.[6] Second generation antihistamines are not expected to be harmful during lactation[2,6] and tend to be preferred because of lack of sedative effects.[6] Human data is only available for loratadine and fexofenadine; these drugs are excreted into breastmilk in small amounts.[2]

**Recommendation:**
**The first generation antihistamines, especially chlorpheniramine, are preferred in pregnancy; if these are not tolerated or effective, second generation agents such as loratadine can be recommended. Due to possible effects on the infant from first generation antihistamines, second generation agents are preferred in lactating mothers.**

## Antitussives

Pregnancy
Codeine is not thought to increase the risk of congenital malformations.[1,2,8] The drug may pose problems if taken close to term: infants born to women in whom codeine was present at labour have developed respiratory depression;[3,4,8] infants born to mothers who took codeine close to term have experienced neonatal withdrawal.[4] Dextromethorphan has not been associated with any problems when taken during pregnancy.[3,4,5,8]

Lactation
Codeine is excreted into breastmilk in small amounts. For the most part, it is considered safe when daily doses do not exceed 240mg.[3,4,6] There is a subpopulation in whom ingestion of codeine while breastfeeding could be risky for the infant – women who are rapid metabolizers of CYP 2D6 convert codeine to larger amounts of morphine, which may be excreted in the breastmilk and be harmful to the baby.[4,6] One case report of such a situation exists.[4] However, codeine has been used very commonly as an analgesic in lactating women. Since CYP 2D6 status is usually unknown, it is best to use codeine with caution in lactation and observe for somnolence in the infant.[6] Neonates in the first two weeks postpartum are particularly sensitive to the effects (apnea has been reported).[2,6] Study of dextromethorphan in lactation has not been undertaken though it is considered safe based on the fact it has been used in young infants.[2,6]

**Recommendation:**
**Dextromethorphan is the preferred antitussive in both pregnancy and lactation, though codeine can be used. More importantly, one needs to consider what degree of benefit will be gained by the mother.**

## Expectorants

Pregnancy
Guaifenesin has been associated with inguinal hernia in one report,[1,3] though others found no increased congenital defects.[3,4,5,8]

Lactation
No studies of transfer to breastmilk are available[2,3,6] though there have been no reports of untoward effects in infants.[2]

**Recommendation:**
**Despite the relative safety of guaifenesin in pregnancy and lactation, the drug has not demonstrated clear efficacy[9] and so is not recommended.[2]**

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