

# Medications and breast-feeding: Current concepts

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## Abstract

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**Objectives:** To describe the various factors that come into play when a breast-feeding mother is taking medications, including use of prescription drugs, over-the-counter medications, recreational drugs, galactagogues, and herbal remedies and to provide a framework used for counseling breast-feeding women.

**Setting:** Community and hospital pharmacy and health care settings.

**Practice description:** Consultative services provided to breast-feeding mothers who had been prescribed or were using medications.

**Main outcome measures:** Use of pharmacokinetic factors, maternal and child factors, a list of questions to ask breast-feeding mothers, and a stepwise approach to counsel breast-feeding mothers on the compatibility of using medications while breast-feeding.

**Results:** By positive intervention of pharmacists and health care providers, up to 1 million breast-feeding mothers, who must use medications, can continue to breast-feed while taking medications.

**Conclusion:** Objectively weighing the benefits of drugs and breast-feeding versus the risks of drugs and not breast-feeding, in most cases, allows for pharmacists to give current and practical advice to mothers and other health professionals who counsel mothers.

**Keywords:** Breast-feeding, pharmacists, medications, counseling (patient), pharmacokinetics, nursing, women's health, lactation.

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**Previous presentations:** At regional WIC and La Leche and Lactation Groups of Maryland, Virginia, Washington DC, Delaware, Arizona, and Maine; at professional meetings for the Maryland Pharmacists Association, the Washington Metropolitan Society of Hospital Pharmacists, the National Association of Pediatric Nurse Practitioners, the Breastfeeding Coalition of the Uniformed Services, and the American Association of Military Surgeons of the United States; at the University of Arizona, University of Virginia, and Johns Hopkins University; and at the NOVA System Hospitals, St. Agnes Hospital, National Institutes of Health Clinical Center, Johns Hopkins Hospital, Union Hospital, and Greater Baltimore Medical Center.

Although the benefits of breast-feeding are widely recognized, pharmacists and other health professionals may advise mothers not to breast-feed when taking medications. This may be considered a prudent action to avoid harming the breast-fed infant; however, practical experience and available data show that compatibility between pharmacologic treatment and breast-feeding is often possible. In fact, given the immunologic and other benefits of breast-feeding, it may be more beneficial for the infant to be breast-fed even when mothers must use medications. Also, methods have been developed for ensuring the safety of medications while breast-feeding.

Mothers may be discouraged from breast-feeding their babies, leading to an unnecessary absence of the healthy effects of breast-feeding on both mother and child. In 2006, approximately 1 million mothers stated that “[they] had to take medicine and didn’t want [their] baby to get it” as the reason they discontinued breast-feeding. By the positive intervention of pharmacists, who would evaluate the compatibility of medication with breast-feeding and follow developed methods of counseling patients, more than 4.3 million mothers giving birth and babies being born each year could benefit greatly.<sup>1</sup>

## Objectives

Various factors come into play when a breast-feeding mother is taking medications. Issues discussed in the current work include the use of prescription drugs, over-the-counter (OTC) medications, recreational drugs, galactagogues, and herbal remedies by breast-feeding women. A framework used in counseling breast-feeding women is provided.

## Pharmacokinetics factors

Several relevant factors should be considered when determining whether a drug is compatible for a breast-feeding mother.<sup>2</sup> The three most important factors are the volume of distribution ( $V_d$ ), the percentage of maternal protein binding (PB), and the molecular weight (MW).

$V_d$  describes how widely the medication is distributed in

the body. Drugs with high  $V_d$  may enter different compartments of the body, therefore resulting in a lower concentration in the blood. These drugs may take a longer time to clear from the body than drugs with lower  $V_d$ . However, drugs may have different elimination half-lives in the plasma and peripheral compartments; thus, drugs with a high  $V_d$  may produce lower milk levels.

Drugs that have a  $V_d$  between 1 and 20 L/kg are generally compatible for breast-feeding.

PB shows the extent to which a drug is bound to the plasma albumin and other proteins. Therefore, drugs that have high PB would generally reduce the infant’s exposure to the medication.

Drugs that have a PB greater than 90% are usually compatible for breast-feeding. For example, the beta-adrenergic blocking drug atenolol has low PB of 6% to 16% and therefore would be more extensively excreted into breast milk.<sup>3</sup>

The MW of a medication is important for determining the entry of a medication into human milk. Medications with small MWs can easily pass into the milk through the small pores in the cell walls of the mammary epithelium. Drugs with higher MWs must be actively transported or dissolved in the cells’ lipid membranes, making drugs with higher MWs less likely to pass into breast milk.

Drugs with MWs more than 800 Da are excluded from the milk compartment more readily than those with MWs less than 800 Da, making them more compatible for breast-feeding. Heparin, interferons, and insulin, for example, are compounds with large MWs and are unlikely to contribute to toxic drug concentrations in breast milk.

## Other pharmacokinetic factors

**pH.** Because breast milk is more acidic than plasma, drugs with a high pH may concentrate more in breast milk than plasma. Conversely, compounds with a low pH may have lower concentrations in breast milk than plasma.<sup>4</sup> It should be noted that although aspirin has a low pH, it may cause Reye’s syndrome in children and therefore is not recommended while breast-feeding.<sup>2,5</sup>

**logP.** Drug molecules that are water soluble are less likely to concentrate in the breast milk. This occurs because water-soluble substances repel fatty substances, and breast milk has a higher fat concentration than plasma.

**$T_{max}$ .** The amount of a drug in the breast milk and in the plasma usually reaches a proportional equilibrium (see milk-to-plasma ratio below.) When a higher drug concentration is present in plasma, the drug concentration in breast milk is generally higher as well. By avoiding feeding the infant at the time the drug reaches its maximum concentration in the plasma ( $C_{max}$ ), the mother can decrease the likelihood of exposing her infant to the drug.

**$t_{1/2}$ .** Infant exposure to drugs in breast milk can be minimized by using drugs with shorter half-lives and thus shorter peak intervals. Doing so allows the drug to reach a low plasma concentration more frequently and allows the mother to time her feedings to correspond to trough levels. After five half-lives, approximately 97% of drug is eliminated from breast

### At a Glance

**Synopsis:** Several factors should be considered regarding medication use in breast-feeding mothers. Use of prescription drugs, over-the-counter (OTC) medications, recreational drugs, galactagogues, and herbal remedies by breast-feeding women are considered in the current work, and a framework used for counseling breast-feeding women is provided.

**Analysis:** A wealth of information on breast-feeding and medications is now available. Ultimately, pharmacists and other health professionals need to weigh the benefits of drug use and breast-feeding against the risks of drug and formula use (i.e., not breast-feeding). Given the immunologic and other benefits of breast-feeding, it may be more beneficial for the infant to be breast-fed even when mothers must use medications.

milk. If the elimination half-life of a drug is 12 to 24 hours or longer, the drug will have the potential to accumulate in the breast milk over time.

**Milk-to-plasma ratio.** The milk-to-plasma ratio (M/P) shows the proportion of drug concentration in the milk versus the plasma. The M/P of a drug and active metabolites is calculated by dividing the drug levels in the milk by the drug levels in the plasma. If M/P is less than 1, it is usually safe to breast-feed.

**Active transport.** Although most medications are passively diffused into breast milk, carrier-mediated active transport does exist for certain medications. Examples of drugs that are actively transported include nitrofurantoin, cimetidine, ranitidine, iodides, and acyclovir.<sup>6-9</sup>

**Relative infant dose.** The relative infant dose (RID) is calculated by dividing the theoretical infant weight-adjusted dose supplied via breast milk by the maternal weight-adjusted dose. When RID is less than 10% of maternal dose, the medication is considered generally safe for breast-feeding. RID gives a good estimate of the amount of maternal dose received by the infant. This concept is explained by the following example:

A 50-kg mother is receiving 500 mg of a drug q.i.d. while breast-feeding her 5-kg infant. The theoretical infant dose of this particular drug is 10 mg/day. (This measurement must be obtained from literature providing drug concentrations in breast milk and the estimation that infant intake is 150 mL milk/kg/day.) The first step in calculating RID is to normalize (or weight adjust) the maternal and infant dose. The preferred unit for calculation is mg/kg/day. The mother is taking the medication four times a day and therefore is receiving a total dose of 2,000 mg/day. Therefore, (1) maternal weight-adjusted dose is  $2,000 \text{ mg}/50 \text{ kg/day} = 40 \text{ mg/kg/day}$  and (2) infant weight-adjusted dose is  $10 \text{ mg}/5 \text{ kg/day} = 2 \text{ mg/kg/day}$ . RID can be obtained by dividing (2) by (1):  $(2 \text{ mg/kg/day})/(40 \text{ mg/kg/day}) = 1/20 = 5\%$ .

Generally, if the RID of a certain drug is less than 10% of the maternal dose, the drug is safe to use during breast-feeding. The drug in the example has an RID of 5% and therefore should be considered safe.

### Maternal and child factors

In addition to the properties of drugs, several maternal and child factors are important to consider for breast-feeding mothers on medication therapy. For example, the mother's mammary epithelium may have drug-metabolizing capacity. As mentioned above, some drugs are actively transported in the mammary epithelium. Additional factors include milk volume and fat content. Milk volume is usually greatest in the early morning, while the fat content of milk is usually highest in the late morning. Because a larger volume of milk in the breast during the early morning is likely, taking drugs at that time would result in a higher drug concentration in the breast milk. Mothers are advised to breast-feed first, then take their medication, thereby decreasing the likelihood of any overexposure to the infant. Similarly, it would be optimal for mothers to take drugs that are less lipid-soluble in the late morning because

they are less likely to be dissolved in the fatty, late-morning breast milk. Finally, the stage of breast-feeding is another maternal factor that should be taken into consideration during medication therapy.

### Breast-feeding schedule

When an infant is first born, mothers are instructed to breast-feed every 1.5 to 3 hours, around the clock. Because the newborn's stomach size is only 5 to 7 mL and the mother's milk supply is not fully developed, the infant cannot take in a larger feeding.

### Development of the mother's milk

**Colostrum.** At 0 to 3 days after parturition, the mother produces colostrum. It is thicker than mature milk, higher in protein and antibodies, and acts as a laxative for the baby.<sup>10,11</sup>

**Transitional milk.** At 4 to 7 days after parturition, the mother produces transitional milk, which contains high levels of fat and lactose and helps the baby regain weight lost after birth.<sup>10</sup>

**Mature milk.** At 7 to 10 days after parturition, the mother starts producing mature milk. Consisting largely of water, mature milk is necessary to maintain hydration for the infant. The milk also includes carbohydrates, proteins, and fats that are necessary for both growth and energy. Mature milk is further classified into foremilk and hindmilk. Foremilk is found during the beginning of a feeding session and contains more water, vitamins, and protein. Hindmilk occurs after the initial release of milk and contains higher levels of fat and aids in the weight gain of infants.<sup>12</sup> The different stages of breast-feeding can affect the amount transfer of lipid-soluble drugs into breast milk.

Infant factors also play a role in determining drug safety. Infants also have the ability to absorb, detoxify, and excrete drugs, although the extent differs. Infants have a high percentage of total body water, and thus higher doses (per kilogram body weight) of water-soluble drugs are required because a higher percentage of their body weight is water. Infants' skin has an immature stratum corneum that can increase exposure to applied topical medications. In some cases, their clearance of drugs (e.g., theophylline, phenytoin) is higher than in adults.<sup>13</sup> An infant's gastric system is not well developed, resulting in a less acidic (more alkaline) environment that can alter the rate and amount of drug absorption and metabolization; their gastrointestinal (GI) transit time also is prolonged because of slower motility. The low amounts of some metabolic enzymes in the GI tract, liver, kidney, and brain also play a role in an infant's ability to metabolize drugs. Other infant factors include genetics, environment, diseases, types of treatment, and growth and development. All of these factors contribute to the complexity of determining the compatibility of medication therapy with breast-feeding. Therefore, pharmacists should consider all factors when evaluating the safety outcome of medication therapy in breast-feeding mothers.

### Questions to ask mothers

During the evaluation of individual patient cases, a pharmacist may use the following questions to aid mothers in determin-

ing appropriate tactics for making medication therapies more compatible with breast-feeding:

- What is the name, strength, and dosage form of the drug? This is the basic information needed to evaluate any situation involving drug use.
- Do you still have the prescription, or have you already filled it and are taking the drug? Asking this question helps get the proper perspective regarding the stage of the drug or breast-feeding situation being evaluated. The mother may be seeking advice on whether to continue breast-feeding if and when she takes the drug. She may be questioning whether she is acting correctly by taking the drug and continuing to breast-feed. She also may have concerns about possible adverse effects on her infant.
- Why is the drug being prescribed? Discuss with the mother whether the drug is essential in a particular situation. This is best decided with the prescribing physician.
- Do you feel you need to take the drug? If the drug is being prescribed for a relatively benign condition, the mother may be willing to endure some personal inconvenience to spare the infant from potential effects of the drug. This also is best decided in conjunction with the prescribing physician.
- What does your physician say regarding breast-feeding outcome and taking the drug? A physician's philosophy about breast-feeding and knowledge of drug effects on breast-feeding can play an important role in his/her opinion as to whether the mother should continue to breast-feed. With knowledge of the physician's views on breast-feeding, the mother can decide whether she wants to further pursue the physician's decision. If a physician's philosophy is in conflict with that of the mother, the mother should seek a second opinion.
- What is the drug dosage schedule and how often do you nurse? If a drug must be taken by a mother and she wishes to continue to breast-feed, scheduling the doses so that peak plasma and milk levels of the drug do not coincide with breast-feeding sessions may be possible. In most cases, it's best for the mother to breast-feed just before taking a dose of a drug and/or at least 2 hours after taking a dose. Short-acting drugs taken on an every-3-to-6-hour schedule usually reach peak plasma and milk levels in approximately 1 to 2 hours.
- How old is the baby? The infant's ability to handle a particular drug usually improves with maturity. It also aids in determining the infant's feeding schedule, which may influence dosage scheduling.
- Was your baby full term or premature? Premature infants have a reduced ability to detoxify drugs.
- What is your baby's weight? This fact may be relevant to the quantity of the drug the baby may be able to tolerate without adverse effects.
- Is your baby currently receiving any medication? Any medication that the infant is receiving can interact with medication the infant receives through breast milk.
- Do you know how to hand express milk or do you have ac-

cess to a breast pump? In some cases, breast-feeding can be stopped temporarily while a drug is administered. In these situations, the mother must hand express milk or pump her breasts to prevent breast engorgement and to maintain her milk supply. The mother can learn to hand express milk or to use a breast pump, if necessary, from lactation consultants or La Leche League consultants.

- Is this your first breast-fed baby? Mothers who have breast-fed in the past will be more knowledgeable of the breast-feeding process. A mother who is breast-feeding for the first time may find it more difficult to come to a decision regarding the use of a drug. Involving a breast-feeding consultant in the process, if acceptable to the mother, may be useful.

### Stepwise approach

After a pharmacist obtains the necessary information to evaluate the patient's case, a safe course of action for the patient should be determined. The following stepwise approach can help patients minimize drug exposure to their newborns:

- Withhold the drug. Avoid using nonessential medications by enlisting the mother's cooperation, with the understanding that maintaining maternal health is of paramount importance. Mothers should be advised to use medications only when necessary and important to their health.
- Try nondrug therapies. Suggested drug-alternative therapies include analgesics (e.g., relaxation techniques, massage, warm baths); cough, cold, and allergy products (e.g., saline nose drops, cool mist, steam); antiasthmatic agents (avoid known allergens, particularly animals); antacids (eat small meals, sleep with head propped, avoid head-bending activities, and avoid gas-forming foods); laxatives (eat high-fiber cereal, prunes, or hot liquids with breakfast); antidiarrheal agents (discontinue solids for 12 to 24 hours, increase fluids, eat toast or saltine crackers).
- Delay therapy. Mothers who are ready to wean their infant might be able to delay elective drug therapy or elective surgery.
- Choose drugs that pass poorly into milk. Large differences in drug distribution into breast milk exist among class members within some drug classes.
- Choose more breast-feeding-compatible dosage forms. Take the lowest recommended dose, avoid extra-strength and long-acting preparations, and avoid combination ingredient products.
- Choose an alternative route of administration. Local application of drugs to the affected maternal site can minimize drug concentrations in milk and, subsequently, the infant dose.
- Avoid nursing at times of peak drug concentrations in milk. Nursing before a dose is given may avoid the peak drug concentrations in milk that occur about 1 to 3 hours after an oral dose. This works best for drugs with short half-lives.
- Administer the drug before the infant's longest sleep period. This will minimize the infant's dose and is useful for long-acting drugs that can be given once daily.

- Temporarily withhold breast-feeding. Depending on the estimated length of drug therapy, nursing can be temporarily withheld. Mothers may be able to pump a sufficient quantity of milk beforehand for use during therapy. The pharmacokinetics of the drug must be examined to determine when the resumption of breast-feeding is advisable.
- Discontinue nursing. A few drugs are too toxic to allow nursing and are necessary for the mother's health. Although most drugs appear in breast milk to some degree, the levels usually do not exceed 1% to 2% of ingested maternal dosage. Thus, the amount of drug an infant receives from the mother often is negligible. For example, an infant may receive only about 10 µg when the mother takes 1 mg of a drug or receive 10 ng when the mother takes 1 µg of the drug. Keeping in mind that the infant has his/her own drug-metabolizing system also is important.

**Recreational drug use**

The composition of breast milk remains virtually unchanged even when a mother has a cold, eats junk food, or suffers from malnutrition.<sup>14</sup> However, it should be noted that drugs that are likely to cross the blood–brain barrier also are likely to cross into breast milk. Therefore, one must question the consequences of taking recreational drugs, especially during the period of breast-feeding.

If recreational drugs are used, breast-feeding should be interrupted for 24 to 48 hours (24 hours for cocaine) after the last dose. The half-lives for each metabolite may prolong the unsafe duration of the drug. Even with interrupted breast-feeding, infants still may test positive for drugs for days or weeks. Extreme caution should be taken if taking cocaine, LSD, phen-cyclidine (e.g., angel dust, PCP), hallucinogenic drugs, amphetamines, or I.V. heroin. PCP and cocaine may be the most dangerous, as the drugs may remain in the baby's system for

**Table 1. Major galactogogues<sup>23,26</sup>**

Major galactogogue	Common daily dose <sup>a</sup>	Interesting facts
Blessed thistle	2–6 g	(1) Blessed and milk thistle are two distinct herbs. (2) Other thistles also may be used as galactogogues.
Milk thistle	12–15 g	See above
Chaste tree fruit	30–40 mg	(1) Also known as chasteberry and vitex. (2) If used in higher doses for breast pain, may affect nursing performance negatively.
Fennel	100–600 mg	Also may aid in milk ejection.
Fenugreek	6 g	(1) Most commonly used herbal galactogogue. (2) Do not use if allergic to peanuts or legumes. (3) Mother and baby may smell like maple syrup.
Garlic	4–9 g	Increases nursing time if baby likes the smell or garlic. The opposite may occur if the baby does not like the smell.
Goat's rue	1–2 mL tincture	(1) Contains galegin, a precursor of metformin. (2) Metformin and galegin show galactogogue properties (increased milk production in goats, sheep, and cattle).

<sup>a</sup>Dosage forms are the same as those for the minor galactogogues and include teas.

**Table 2. Minor galactogogues<sup>23,26</sup>**

Minor galactogogue	Common daily dose <sup>a</sup>	Interesting facts
Alfalfa	60 g maximum	(1) Do not use if allergic to peanuts or legumes. (2) Do not use if the mother has systemic lupus erythematosus.
Anise	10–42 g	The mild estrogenic properties may aid in milk ejection.
Borage	1–2 g	Potential blood thinner in large amounts.
Caraway	1.5–6 g	Avoid volatile oil form.
Coriander	3 g	Also known as cilantro.
Dandelion	15 g	Contraindicated in bile duct blockage and bowel obstruction.
Dill	3 g	Acts as a diuretic to reduce postpartum edema.
Hops	500 mg or one bottle of stout beer	Aids milk let down.
Marshmallow root	3 g	(1) Not the same as the Kraft variety. (2) Acts as a diuretic.
Nettle	1.8 g	Acts as a diuretic.
Oat straw	100 g	Same as regular oatmeal.
Red clover	40–80 mg	(1) Avoid fermented type. (2) Potential blood thinner.
Red raspberry	2.7 g	(1) May aid in milk ejection. (2) May decrease milk supply after 2 weeks of use.
Vervain	30–50 g	Contraindicated in pregnancy because of oxytocic properties.

<sup>a</sup>Dosage forms are the same as those for the minor galactogogues and include teas and beer (hops).

weeks after the last maternal dose. In addition to the long half-life of the parent drugs, their metabolites have very long half-lives.

Social considerations related to recreational drug usage include how frequently and how much the mother takes, as well as her ability to care for her baby while under the influence. Mothers on recreational drugs need to be assessed for their dependability. Pharmacists should recommend high-risk mothers to discontinue breast-feeding, while low-risk mothers should be given the details of drug transfer into the breast milk and the hazards of the drug to their babies. Pharmacists should let the mother know the hazards of hepatitis B and HIV transfer to the unprotected baby should the mother become infected. Mothers need to know that the baby will test positive during drug screenings for a very long period of time after the mother initially took the drug, as well as the legal consequences of drug screen tests in babies.

Questions often arise regarding use of methadone (i.e., narcotic pain reliever used to reduce withdrawal symptoms in narcotic addicts) during the period of breast-feeding. Research has shown that the methadone concentration remains low in the breast milk such that the potential infant exposure is unlikely to have any negative effect on the developing child. Even at a maximal allowable pediatric dose of 270 µg/day, no serious health or developmental concerns have been observed. When an infant or a pediatric patient needs to be weaned from narcotics, the drug of choice also is methadone. It is given at a low dose of 0.1 mg/kg/dose every 4 hours. The half-life in pediatric children is less than adults (children  $t_{1/2} = 19 \pm 14$  hours; adult  $t_{1/2} = 35 \pm 22$  hours), which means that less exposure to the infant or pediatric patient occurs. Therefore, mothers using methadone are recommended to continue breast-feeding.<sup>15</sup>

Health professionals often are consulted regarding the use of alcohol. Alcohol rapidly exchanges between the plasma and breast milk. One study has shown that mothers' alcohol use showed a 23% reduction in the amount of milk ingested by ba-

bies.<sup>16</sup> The reduced ingestion may be a result of the taste of alcohol in milk. Recent studies suggest that alcohol suppresses oxytocin levels, which reduces milk ejection.<sup>17</sup> It is more reassuring to know that maternal blood alcohol levels must reach 300 mg alcohol in 100 mL blood before affecting the infant considerably.<sup>2</sup> Mothers consuming alcohol can resume breast-feeding after moderate alcohol use as soon as the affects of the alcohol have passed. Pharmacists should also recommend interrupting breast-feeding if the mother consumes more than one drink per hour.

Cigarette smoke is known to cause a substantial decrease in milk production. Although the exact physiology is unknown, the combination of lower levels of prolactin, elevated somatostatin levels after episodes of suckling, and impaired oxygen delivery and blood flow to the mammary gland may result in lower milk production.<sup>18</sup> As a result, the baby's nursing behavior may change. Also, a significant increase of infantile colic has been observed.<sup>19</sup> Milk fat, a crucial component in the baby's development and weight gain, was shown to be at least 19% lower in smoking mothers.<sup>18</sup> Nicotine cessation therapy should be recommended to smoking mothers, and nicotine replacement therapy such as nicotine patches or gum are good as adjuncts to therapy.<sup>20,21</sup> Nicotine patches with appropriately managed doses were demonstrated to decrease the absolute infant intake of nicotine and its metabolite. Patches not only prevent the rapid entry of nicotine into breast milk but also reduce the infant's exposure to a cigarette smoke-contaminated environment and, through the mother's metabolism, stop exposure to the direct pharmacologic actions of nicotine, its metabolite, and other toxic substances derived from the cigarette.<sup>21</sup>

**Galactogogues**

Besides the influence of medication on breast milk, mothers often are concerned about an inadequate quantity of breast milk. Many patients will attempt to increase the quantity of breast milk production by taking herbs and foods called galac-

**Table 3.** Contraindicated and alternative herbal remedies<sup>25,26</sup>

Indication	Contraindicated	Recommended alternative
Major galactogogue	NA	Chaste tree, fennel, fenugreek, garlic, goat's rue, milk thistle
Analgesics	Comfrey	Bugleweed <sup>a,b</sup>
Headache (migraine) agents	Feverfew	NA
Cough, cold, and allergy products	Coltsfoot	Echinacea, elder flower
Gastrointestinal agents	Aloe, buckthorn, cascara sagrada, licorice, rhubarb, senna	Flaxseed, psyllium seed (blonde), chamomomile
Nausea and vomiting preparations	NA	Ginger
Lipid-lowering agents	NA	Soy lecithin
Urinary tract preparations	Petasites, uva ursi	Goldenrod
Antianxiety agents	Indian snakeroot, kava kava	Passionflower, <sup>a</sup> St. John's wort, <sup>a</sup> valerian <sup>a</sup>
Sleep preparations	NA	Melatonin

Abbreviation used: NA, not applicable.  
<sup>a</sup>Monitor nursing for potential adverse effects.  
<sup>b</sup>May decrease prolactin level.

togogues. These substances increase milk supply, usually by increasing prolactin to initiate the breast milk let-down reflex or oxytocin to aid in breast milk ejection.

Commonly used galactogogues include blessed thistle, chaste tree fruit, fennel, fenugreek, garlic, goat's rue, and thistles. Categorized as major galactogogues, they are the primary herbs used as galactogogues and are commonly used alone. Other herbs that also may act as galactogogues include alfalfa, anise, borage, caraway, coriander, dandelion, dill, hops, marshmallow root, nettle, oat straw, red clover, red raspberry, and vervain. These are considered minor galactogogues because they are not as commonly used and are generally used in combination with other galactogogues, often in homeopathic preparations. If one looks at the lists of both major and minor galactogogues, it is apparent that many of these herbs are useful in food products, especially within particular ethnic groups. Tables 1 and 2 summarize the doses and facts about the major and minor galactogogues. Although claims of these products promoting the production of breast milk often are anecdotal reports,<sup>22</sup> the products are widely used within the breast-feeding community, often with success.<sup>23</sup> Resources providing lists of common uses of foods and herbs are available, but evaluations according to pharmacokinetic and pharmacodynamic guide-

lines are not provided (see relevant breast-feeding websites in SUMMARY).

**OTC medications**

Classes of OTC medications that are commonly used by breast-feeding women include analgesics; cough, cold, and allergy preparations (including lozenges, inhalers, drops, rubs, sprays, and nasal preparations); asthma preparations; antacids and digestive aids; laxatives and stool softeners; anti-diarrheal preparations; nausea, vomiting, and motion sickness preparations; hemorrhoidal preparations; sleep preparations; stimulants; appetite suppressants; insulin preparations; artificial sweeteners; oral hygiene products; heart attack risk reduction medications; pinworm treatments; smoking aids; vaginal infection products; eye and ear medications; and a wide variety of topical formulations. In most cases, ingredients of eye, ear, and topical OTC preparations should not appear in breast milk in harmful quantities. If skin preparations are required for sore or cracked nipples, care creams specific for this condition should be used. Vitamins and minerals in daily recommended doses are safe for nursing mothers to take.<sup>24</sup>

In many cases, OTC medications consist of multiple ingredients for multiple symptoms. Many OTC products have both

**Table 4.** Overview of relevant breast-feeding websites

American Academy of Pediatrics (AAP). The transfer of drugs and other chemicals into human milk [policy statement]. <a href="http://aappolicy.aapublications.org/cgi/reprint/pediatrics;108/3/776.pdf">http://aappolicy.aapublications.org/cgi/reprint/pediatrics;108/3/776.pdf</a> . The AAP policy statement provides important concepts regarding the use of cigarettes, psychotropic drugs, and silicone implants while a mother is breast-feeding. It is well referenced, and seven tables regarding the statement are provided.
Breastfeeding Online. <a href="http://www.breastfeedingonline.com">www.breastfeedingonline.com</a> . Cindy Curtis, a registered nurse and International Board Certified Lactation Consultant developed the website to help empower women to choose to breast-feed and to educate society on the importance and benefits of breast-feeding. She provides therapies for mastitis, thrush, engorgement, insufficient milk supply, and nipple vasospasm, among others.
National Library of Medicine (NLM). Drugs and Lactation Database (LactMed). <a href="http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT">http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT</a> . Philip O. Anderson, a leading pharmacist breast-feeding expert, originated LactMed as a peer-reviewed and fully referenced NLM database of drugs to which breast-feeding mothers may be exposed. Maternal and infant levels of drugs, possible effects on breast-fed infants and on lactation, and alternate drugs to consider can be found here.
Thomson Reuters. Micromedex health care series. <a href="http://www.micromedex.com/products/hcs">www.micromedex.com/products/hcs</a> . For most drugs in Micromedex, current information and corresponding references are listed under "Breast feeding." If insufficient information is listed under this category, it can be found under "Pharmacokinetics" with the subsections "Distribution," "Metabolism," and "Excretion." In evaluating the pharmacokinetics of the drug to see if it is compatible with breast-feeding, the guidelines for presented in this article can be used.
Natural Standard. <a href="http://www.naturalstandard.com">www.naturalstandard.com</a> . After clicking on "Databases" at the top of the website, click on "Foods, herbs & supplements." This section covers extensive monographs on specific foods, herbs, and supplements, including a "Pregnancy & lactation" section. However, safety data often suggest that breast-feeding is not safe because of a lack of evidence.
Therapeutic Research Faculty. Natural Medicines Comprehensive Database. Overview: <a href="http://www.naturaldatabase.com">www.naturaldatabase.com</a> . The website contains a large selection of natural medications, each with a detailed monograph. The monographs provide the common names; scientific names; uses; safety details; adverse reactions; interactions with drugs, foods, and other herbs and supplements; diseases/conditions; and dosage of the particular medication. In the safety section of the monograph, a pregnancy and lactation section provides how "likely" the medication is to be safe to consume while pregnant or lactating, despite data often not being available. The likelihood of safety in lactation is often backed up with general uses or the amount contained in a normal diet.
Nice FJ. Nice Breastfeeding. <a href="http://www.nicebreastfeeding.com">www.nicebreastfeeding.com</a> . The website provides counseling tips for pharmacists (included in this article), as well as a compilation of useful breast-feeding websites. Health professionals may contact Dr. Nice for consultation advice at no cost through the website.
Hale TW. Breastfeeding pharmacology. <a href="http://www.infantrisk.org">www.infantrisk.org</a> . Dr. Hale is a leading expert in the use of medications in breast-feeding women. He offers answers to questions by health professionals only, through a medication forum on the website. However, the information is accessible by the public. In addition to the medication forum, a wealth of breast-feeding information is compiled.

regular- and extra-strength forms. In addition, medications may be short or long acting. There are OTCs that have the same root name for multiple formulations. For example, Maalox Total Relief includes bismuth subsalicylate and Maalox Maximum Strength has three active ingredients (aluminum hydroxide, magnesium hydroxide, and simethicone).

To help mothers make informed decisions regarding OTC product use during breast-feeding, the following counseling guidelines are offered:

- Avoid taking OTC products for which little breast-feeding information is available. Pharmacists should be able to provide additional information.
- Avoid taking OTC products for which safer products are available. Pharmacists should be able to help determine alternatives.
- Avoid taking combination OTC products, which are those with multiple ingredients. It is better for mothers to take OTCs that have the one or two specific ingredients that will treat a specific condition; mothers or breast-feeding infants should not be exposed to unnecessary ingredients.
- Avoid taking extra-strength forms of OTC products. Again, breast-feeding infants should not be exposed to higher levels of a drug.
- Avoid taking long-acting OTC products. Infants should not be exposed to a drug for longer than necessary, especially if an adverse reaction is possible.
- Mothers should know the exact OTC ingredient(s) and possible adverse effects that might occur in infants and themselves. Pharmacists can advise.
- If possible, mothers should first use nondrug approaches to treat symptoms.

**Herbal remedies**

As with prescription drugs and OTC products, breast-feeding mothers use herbs to treat a variety of ailments and to maintain health. Herbal remedy use is as prevalent among breast-feeding women as it is among patients who are not breast-feeding.

Herbal remedies provide the opportunity not to use a prescription or OTC medication. Nursing women who use herbal remedies should approach their use cautiously, however. Many manufacturers promote their products as “natural”; however, that does not always imply that using them is safe or compatible with breast-feeding. Unlike the regulation of prescription and OTC medications, the Food and Drug Administration (FDA) does not regulate herbal products in the same manner. Instead, FDA regulates herbal remedies under food manufacturing regulations: They are required to be free of contaminants, and labeling of herbal remedies may not make unfounded health or medical claims. In summary, no government regulation of herbal remedy use as drugs exists, and government-regulated standardization does not exist for herbal preparations. As a result, active ingredients may be present in higher or lower amounts than that stated on the labeling of the herbal product. Unknown, potentially harmful ingredients also may be present. Strengths of herbal product ingredients may vary depending on the particular plant used, the part of the plant used, and where, when, and how the herb was processed. These inconsistencies can lead to differences in efficacy and potentially harmful adverse effects in the mother and/or infant.<sup>25</sup>

Most lactation knowledge about potential adverse effects of the wide variety of herbal remedies comes from the systematic collection of data in Germany (i.e., the German Commission E monographs, which have been translated into English).<sup>26</sup> There have been reports of specific herbal adverse effects, but standardized methods of reporting these adverse effects are lacking. As with all medications, breast-feeding women should have a real need for treatment before taking herbal preparations. Depending on the condition being treated, conventional medications, if possible, should be considered first-line therapy until more controlled studies and data are available for specific herbal remedies. Table 3 contains information on commonly used herbal remedies by nursing mothers and provides general guidelines.

**Table 5. Benefit-to-risk analysis of medication use when breast-feeding or not breast-feeding<sup>27-29</sup>**

Benefits of breast-feeding	Disadvantages of not breast-feeding
Bonding of mother and child	
Better recovery with less blood loss at birth.	Breast-feeding decreases postpartum hemorrhage by increasing level of oxytocin, which stimulates uterine contractions.
Delays return of a woman’s ovulation and menstruation for a viable 20 to 30 weeks or more, providing a natural means of child spacing for many.	Premenopausal breast cancer, ovarian cancer, heart disease, osteoporosis, anemia, obesity, type 2 diabetes for women without a history of gestational diabetes.
Infant receives (1) immunoglobulin; (2) enhanced immune response to inoculations against polio, tetanus, diphtheria, influenza; (3) nutrients; (4) growth factors; (5) lipoproteins/cholesterol needed for brain and nerve development.	Infants will have increased risks of (1) SIDS (sudden infant death syndrome), (2) infectious diseases (diarrhea, ear infections, upper respiratory tract infections, meningitis), (3) bowel diseases (Crohn’s disease, ulcerative colitis), (4) cancer (Hodgkin’s disease, leukemia), (5) diabetes, (6) obesity, (7) asthma, (8) eczema, (9) cavities, (10) decreased IQ (by 8–15 points), (11) acute infections (diarrhea, pneumonia, ear infection, <i>Haemophilus influenza</i> , meningitis, urinary tract infection).
In adolescent and adult life of infant: (1) lower mean blood pressure, (2) lower total serum cholesterol, (3) lower prevalence of type 2 diabetes.	Chronic conditions in the future: (1) increased risks of ulcerative colitis, (2) increased risks of Crohn’s disease, increased risks of type 1 diabetes.



## Summary

The number of reliable resources regarding medications and breast-feeding has increased considerably during the previous 40 years. A wealth of information is now available, as evidenced by the overview of relevant breast-feeding websites provided in Table 4. Ultimately, health professionals need to weigh the benefits of drug use and breast-feeding against the risks of drug and formula use (i.e., not breast-feeding). Table 5 summarizes the benefits of breast-feeding and the disadvantages of not breast-feeding. By counseling breast-feeding mothers, pharmacists and other health professionals can make positive contributions to the health of mothers and babies.

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