

# Drugs in breastmilk

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1.25  
CEUs

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## Learning objectives

Upon successful completion of this lesson, you should be able to:

1. State the definition of "exclusive breastfeeding" and Health Canada's recommendation on exclusive breastfeeding
2. Describe the benefits to mother and baby of breastfeeding
3. Discuss risk versus benefit of maternal drug use during breastfeeding versus weaning to infant formula
4. Suggest ways to minimize a breastfeeding infant's exposure to or potential harm from drugs via breastmilk
5. Discuss drugs and substances ingested by the mother that can change the quantity and quality of breastmilk
6. Counsel a mother on commonly used prescribed and over-the-counter medications, herbs and social drugs during breastfeeding

*To successfully complete the post-test for this lesson, you may need access to the Compendium of Pharmaceuticals and Specialties (CPS) and/or Patient self care (PSC): Helping patients make therapeutic choices.*

Breastfeeding has been shown to set the stage for optimal health, for both baby and mother. Health Canada recommends exclusive breastmilk feeding for healthy term infants for the first six months, and breastfeeding with complementary foods for up to two years and beyond.<sup>1</sup> This recommendation is also endorsed by the College of Family Physicians of Canada, the American Academy of Pediatrics and the Canadian Paediatric Society.<sup>2,4</sup> Exclusive breastfeeding means the baby is receiving *only* breastmilk with no other liquids (including water) or solids, with the exception of undiluted drops or syrups (vitamins, miner-

al supplements, or medicines).<sup>5</sup>

Despite breastfeeding's unquestionable benefits (Table 1), many women are nervous about ingesting medications when they are breastfeeding, in an echo of their fear of harming their babies *in utero*. These women may decide to use artificial milk rather than breastfeed, or may decide to discontinue their drug therapy in this period.<sup>6,8</sup> They may not know that the vast majority of medications pose no risk to the infant.<sup>7,9</sup> Health professionals, including pharmacists, can play an important role in educating mothers about this issue, and help them understand that in most cases

breastfeeding and drug therapies can both be continued.

Endorsement of the WHO Baby-Friendly Initiative<sup>5</sup> by Health Canada and the member health professional organizations of the Breastfeeding Committee for Canada (BCC) ([www.breastfeedingcanada.ca](http://www.breastfeedingcanada.ca)) is changing the cultural status quo of breastfeeding from a lifestyle choice to a health choice.

This lesson focuses on drugs and breastfeeding, reviewing the various factors that influence drugs in breastmilk. It is also intended to help the pharmacist help mothers with safe and healthy breastfeeding practices. See Table 2 for resources for pharmacists on the normal course of breastfeeding and distance education courses on breastfeeding.

## Why is breastfeeding important?

"Colostrum," the first of mothers' milk, coats the newborn's gut, preventing exposure to harmful organisms and foreign substances. It closes the gut, thus decreasing permeability. Secretory IgA (secretory immunoglobulin A), which is present in breastmilk, provides an ongoing "vaccination" (adaptive immunity) to harmful bacteria and viruses in the baby's environment that continues through weaning and beyond. Innate immunity in breastmilk (neutrophils, macrophages, lymphocytes), cytokines (anti-inflammatory factors) and lactoferrin further protect the baby's gut. Growth factors (epidermal; insulin-like) and

## Instructions

1. After carefully reading this lesson, study each question and select the one answer you believe to be correct. Circle the appropriate letter on the attached reply card.
2. Indicate if you are already registered as an annual CE Club Member or if you would like to become a member.
3. Complete the card, and mail or fax to (416) 764-3937.
4. Your reply card will be marked and you will be advised of your results within six to eight weeks in a letter from *Pharmacy Practice*.
5. To pass this lesson, a grade of 70 per cent (14 out of 20) is required. If you pass, your CEU(s) will be recorded with the relevant provincial authority(ies). (Note: some provinces require individual pharmacists to notify them.)

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hormones (leptin, growth hormone, prolactin) in human milk further benefit the baby's growth and health. Long chain polyunsaturated fatty acids (LCPUFAs) in human milk are responsible for optimal visual acuity and cognitive development.<sup>1,10</sup> Human milk adapts to the needs of the growing baby, providing hydration and nutritional building blocks for the creation of a healthy human body. The longer a child is breastfed, the more protection is received; benefits are "dose-dependent."<sup>16</sup>

There is evidence to show that mothers also garner health benefits from breastfeeding (see Table 1).

### Risks of artificial baby milks and soothers

Artificial milks, either soy or cow milk-based, have risks. They are devoid of the innate and adaptive immunities mothers provide for babies, and so can replace but cannot duplicate human milk. LCPUFAs have been added to artificial milk to more closely duplicate human milk; however, a Cochrane systematic review of the literature on this has not shown it to be of benefit to term or premature infants.<sup>17</sup> Inappropriate use of soothers in breastfed infants (originally designed to provide sucking stimulation for artificially fed infants) may limit milk-producing suckling and emptying of the breast, and weight gain<sup>3,18</sup> (see Table 3).

### Products that affect milk quantity and characteristics

Some drugs not only appear in breastmilk, but also change its quantity and characteristics.

If a woman comes to the pharmacy asking about artificial baby milk because she thinks she is unable to produce enough breastmilk, the pharmacist should ascertain why the mother thinks her milk supply has changed, and whether she has consulted a breastfeeding expert (see Table 2) or her family doctor. Many mothers erroneously conclude they are producing inadequate amounts. If a mother does have a decrease in milk supply, the pharmacist

**TABLE 1** Breastfeeding benefits to baby and mother<sup>1-3,10-14</sup>

For baby
<ul style="list-style-type: none"> <li>• decreased incidence and/or severity of gastrointestinal infections</li> <li>• lower rate of respiratory and middle ear infections</li> <li>• possible protective effect against sudden infant death syndrome (SIDS), insulin-dependent and non-insulin-dependent diabetes, Crohn's disease, ulcerative colitis, lymphoma, allergic diseases, hypercholesterolemia</li> <li>• analgesia during painful procedures</li> <li>• optimal cognitive and visual development</li> </ul>
For mother
<ul style="list-style-type: none"> <li>• increased oxytocin lessens postpartum bleeding and speeds uterine involution; oxytocin promotes resistance to stress</li> <li>• lactational amenorrhea causes less menstrual blood loss over the months after delivery and, based on six months of exclusive breastfeeding, iron requirements are lower for breastfeeding mothers whose menses have not returned versus menstruating mothers</li> <li>• earlier return to pre-pregnant weight</li> <li>• improved bone re-mineralization postpartum with reduction in hip fractures in the post-menopausal period</li> <li>• reduced risk of ovarian cancer, endometrial cancer and breast cancer</li> <li>• saves money on prescriptions for baby; saves cost of artificial baby milks</li> </ul>

should look for drug-related reasons for this decrease, and also suggest strategies to rectify the milk supply problem.

**Products causing decreased secretion:**

Drugs that increase dopamine (a prolactin inhibitor) or decrease prolactin secretion inhibit milk production. An example of this would be cabergoline (a dopamine agonist that decreases prolactin). As well, combination estrogen-progestin oral contraceptives can lower milk supply,<sup>19,22</sup> as estrogen has an inhibitory effect on lactation, whereas progesterin does not usually affect milk production.<sup>19</sup> For this reason, progesterin-only contraceptives are recommended for breastfeeding mothers. They are started no earlier than six weeks postpartum as a precaution against theoretical concerns of infant exposure to synthetic hormones<sup>22</sup> and so as not to interfere with the fall in serum progesterone that triggers milk production.<sup>19</sup> Mothers may be started on the tablet product first to check for poten-

tial side effects; if no problems arise on the tablet, the mother may then stay on the tablets, or switch to either the long-acting injection or a progesterone-impregnated intrauterine device (IUD) if desired.<sup>19</sup> It is possible to continue uninterrupted breastfeeding after taking emergency hormonal contraception or the "morning after pill" (progesterin only or Yuzpe method [the combination]).<sup>22</sup>

**Products causing increased secretions:**

The term *galactagogue* describes a drug or herb that can induce lactation.<sup>23</sup> Domperidone has been prescribed 'off label' in early lactation to increase a mother's milk supply in doses up to 20 mg qid.<sup>24</sup> It suppresses dopamine, an inhibitor of prolactin. The rationale is that a high level of the hormone prolactin is necessary in the early days of lactation to turn on the production of milk in the cells of the alveolar sacs of the breast.<sup>25</sup> Early in lactation the stimulus for further production is the level of circulating prolactin (endocrine control); later

## CE Faculty

### This month

Drugs in breastmilk

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### Reviewers

All lessons are reviewed by three pharmacists for accuracy, currency and relevance to current pharmacy practice.

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**TABLE 2** Breastfeeding resources for pharmacists

**Distance education courses on breastfeeding**

**Grant MacEwan College** (AB) 780-497-4511

Self-study distance education non-credit course “Issues in Breastfeeding Practice;” attendance certificate provided

**Mohawk College** (ON) 905-540-4247, ext 26703

“Breastfeeding I” and “Breastfeeding II” courses; distance and in-class; non-credit; attendance certificate provided

**Douglas College** (BC) 604-527-5045

Breastfeeding Counsellor Certificate Program, on-site at Douglas College and some BC and MB universities; also offers the UNICEF 18 Hour Breastfeeding Course & a lactation consultant exam (www.lbce.org) preparation course

**Find a breastfeeding expert**

**La Leche League Canada**

Volunteer lay breastfeeding helpers: 800-665-4324; www.LLLC.ca

**Canadian Lactation Consultant Association**

www.clca-aacl.ca (under Membership, find LCs in Canada)

**Practice interest network on breastfeeding**

An informal email network of pharmacists interested in breastfeeding education and issues.

Go to: www.pharmacists.ca or contact author at jpeddles@telus.net, 403-272-3764

**Read more about breastfeeding**

Peddlesden J. Infant nutrition. In: Patient self care (PSC): Helping patients make therapeutic choices. Ottawa: Canadian Pharmacists Association; 2002.

Canadian Pharmacists Association. Statement on breastfeeding and infant feeding. Ottawa: The Association; 2001. www.pharmacists.ca (accessed January 17, 2005).

**TABLE 3** Risks of artificial baby milks<sup>11,19-21</sup>

- Increased risk of allergic sensitization and atopic eczema
- Toxicity due to bacterial contaminants (*Enterobacter sakazakii*)
- Increased risk of necrotizing enterocolitis in premature babies
- Increased risk of gastrointestinal infections
- Increased risk of respiratory illness and ear infections
- Suboptimal visual acuity
- Suboptimal cognitive development

in lactation it is the removal of milk containing an inhibitory protein (autocrine control). One Canadian randomized, double-blind, placebo-controlled study showed domperidone 10 mg tid was successful in increasing milk supply for mothers of premature babies.<sup>26</sup> Domperidone appears in low levels in breastmilk after oral doses,<sup>19</sup> and recent controversial precautions from the U.S. Food & Drug Administration (FDA) are based on use of the drug intravenously.<sup>27,28</sup>

The use of herbs as galactagogues is based on tradition.<sup>29,30</sup> Alfalfa, milk thistle, blessed thistle, stinging nettle, fenugreek, fennel, red raspberry, cumin, anise, barley, oats, caraway, dill, coriander, marshmallow, vervain, tumeric and goat’s rue have been used individually or in combination in teas, sometimes called ‘mother’s milk tea.’<sup>29</sup> For most herbs traditionally used as galactagogues, the mecha-

nisms of action have not been studied or fully elucidated. Some of these herbs may have an effect by increasing prolactin (the hormone that initially triggers milk production), or by increasing oxytocin (the hormone that initiates milk let-down from the breast through stimulation of the myoepithelial cells surrounding each of the alveolar milk sacs in the breast).<sup>30</sup> Anise, fenugreek, turmeric, goat’s rue and vervain may not be appropriate for self-use by some mother-baby pairs; the rest are safe for self-use in breastfeeding.<sup>29</sup> Because stress inhibits milk let-down, increased milk supply may happen simply because the mother sits down with a cup of herbal tea, rehydrates, relaxes, rests, and lets the milk-producing hormones flow.<sup>31</sup>

Fenugreek has been recommended by naturopaths in therapeutic doses to increase milk secretion.<sup>24,29</sup> It contains diosgenin, a phytoestrogen, which may contribute to its galactogenic activity.<sup>32</sup> One report of 10 cases, where mothers acted as their own controls, showed increased milk supply with doses of three 610 mg capsules tid.<sup>33</sup> Fenugreek should be used with caution in diabetics due to its hypoglycemic properties; as well, it has been known to cause allergic reactions in susceptible individuals, for example a breastfeeding mother with allergies.<sup>29,34</sup>

**Altered characteristics of breastmilk:** It is normal for breastmilk to take on the flavours and colours of the mother’s diet, and this prepares the baby for enjoyment of smells and tastes of the family’s foods.<sup>35</sup> Nutritional sup-

plements, drugs and foods have been implicated in colour or odour change of milk (e.g., alfalfa, kelp, green-coloured sports drinks ==> green milk; B vitamins, excessive carrot ingestion ==> orange milk; minocycline ==> black milk; garlic ==> garlic smell to milk).<sup>19,31</sup>

**Drug levels in breastmilk**

Drugs and herbs appear and disappear from breastmilk primarily through *passive diffusion* from the mother’s plasma into breastmilk, and *retrograde diffusion* back into the plasma as the mother’s body removes the drug. Unlike the kidney, the breast is not a route of elimination of a drug. Almost all the drugs that a mother ingests will be present to some extent in her breastmilk. However, most drugs do not exceed a relative infant dose (RID) of one per cent of the mother’s dose, which is well within generally accepted safety limits. (The RID is calculated by dividing the infant’s dose via milk in mg/kg/day by the mother’s dose in mg/kg/day. See below for a more detailed discussion of RID.)<sup>19</sup>

The only accurate way to measure the dose of drug that transfers to the baby through breastmilk is by taking a steady-state drug blood level in the infant after the drug has reached steady state in the mother. It is possible to obtain laboratory measurements of drug levels in pooled 24-hour samples of breastmilk.

When studies of the presence of a drug in breastmilk are unavailable, the clinician uses the drug’s characteristics to predict its appearance in breastmilk. The most important characteristic is *protein binding*. The higher the protein binding of a drug in plasma, the less it appears in breastmilk (less unbound drug free to pass into the milk). Warfarin is 99 per cent protein-bound in the mother’s plasma, and trace or undetectable amounts appear in milk.<sup>19</sup> Also, drugs must be capable of being *orally absorbed* into the bloodstream of a breastfeeding infant. Some are too large to be orally absorbed and others are destroyed by acid in the infant’s gut. Heparins, which appear in breastmilk, are too large to be orally absorbed, and are also destroyed in the infant’s gut. The high molecular weight of interferons would limit their appearance in breastmilk. Omeprazole would be destroyed by acid in the infant’s gut.<sup>19</sup>

Antibiotics such as an injectable third-generation cephalosporin or gentamicin, although not orally absorbed, may reach the gut and alter the flora, thus causing diarrhea or precipitating a candida (thrush) infection.<sup>36</sup> The drug passes unchanged into the gut, where it can alter the flora by destroying normal healthy gut bacteria. Antibiotic use by a breastfeeding mother poses a theoretical risk of later sensitization in the baby; however, this has not been reported.

The longer the half-life (t<sup>1/2</sup>) of a drug, or the more active the metabolites of a drug, the

more likely it is to accumulate in the system of a newborn or infant whose liver and kidneys are not yet fully mature. The *absolute quantity* of drug ingested by the mother also has an effect—the more doses of a drug, the higher the dose, and the longer the mother's therapy, the more drug her baby will get.

A simple explanation of the pharmacokinetics of drug transfer into breastmilk is available in *Medications in Mother's Milk*<sup>19</sup> or in "How Drugs Enter Breastmilk" (available at <http://neonatal.ttuhs.c.edu/lact/>).

There are a number of terms used in the literature on drugs in breastmilk to report the presence of a drug in breastmilk. The *M/P (milk/plasma) ratio* compares the drug concentration in the breastmilk with that in the mother's bloodstream. Erroneous conclusions regarding risk to the infant result when decisions on drug safety are based solely on the M/P ratio. If plasma and milk levels are at an absolute low level and a M/P ratio favours milk (>1), this paints an incorrect picture of the risk to the baby. Unlike the RID, it is a description of a relationship, not an actual amount of drug transferred to the infant.<sup>37</sup> Where only M/P ratios are reported in literature, an M/P ratio greater than 1-5 may be cause for caution.<sup>19</sup>

The *relative infant dose (RID)* ingested by the infant has been calculated by researchers for a number of drugs. The RID ingested by the infant is determined by laboratory measurement of drug levels from 24-hour mixed samples of breastmilk, and knowing the mother's dose per kg. In this calculation, babies are usually estimated to consume 150 mL/kg/day of breastmilk.<sup>37</sup> An RID that is less than 10 per cent of the mother's dose is generally considered safe.<sup>19</sup>

### Drugs contraindicated during breastfeeding

Few drugs are completely contraindicated during breastfeeding. In 2001 the American Academy of Pediatrics updated their statement on the use of drugs and chemicals during breastfeeding.<sup>38</sup> This statement is updated regularly as case reports and studies become available, new drugs are added, and drugs move from 'contraindicated' to 'use with caution,' or from 'caution' to 'usually compatible,' or vice versa. For example, lithium was once contraindicated, but can now be used with caution so long as monitoring is done of milk levels and the baby's hydration status (since a change in hydration status can alter lithium levels), and of infant blood levels at steady state.<sup>39</sup> Metronidazole, once contraindicated, is now used in breastfeeding mothers.<sup>36</sup> Ultimately, each mother and baby pair must be considered in isolation in questions of risk versus benefit in therapy during breastfeeding.

Mothers should be encouraged to avoid the use of all illegal drugs while breastfeeding, as questions of legality, lifestyle and the baby's

safety arise when mothers use cannabis, cocaine, heroin, hallucinogenic amphetamines (e.g., Ecstasy) or phencyclidine (e.g., Angel Dust).<sup>38</sup> The Canadian Centre on Substance Abuse (<http://www.ccsa.ca/index.asp?ID=62>) estimates that between 10 and 15 per cent of the adult Canadian population has used cannabis in the past year, up from seven per cent in 1994. Although delta-9-THC (the active component of cannabis) levels in breastmilk are not high, a breastfed baby may be at risk for sedation and growth delay and may test positive in urine screens for two to three weeks after exposure.<sup>19</sup>

Drugs that are generally agreed to be contraindicated in breastfeeding mothers are antineoplastic (cytotoxic) drugs, radioactive drugs such as iodine<sup>131</sup>, drugs of abuse, and drugs that inhibit lactation (e.g., cabergoline, a dopamine agonist that decreases prolactin).<sup>19,36,38,39</sup>

### Drugs requiring monitoring

Some drugs with theoretical potential to harm the infant warrant second thinking before prescribing to a breastfeeding mother (see Table 4). For other drugs, it may be prudent to monitor the infant once steady-state blood levels are reached in the mother. Where no studies have been published on a drug's appearance in breastmilk, the clinician uses physicochemical properties to predict appearance in milk and effects on the baby.

### Adverse effects

Of the published reports of adverse events in infants ostensibly caused by prescription or over-the-counter (OTC) medications, few are serious, and few can definitely be attributed to drugs ingested by the mother during breastfeeding.<sup>41,42</sup>

All health professionals encountering adverse effects in breastfeeding infants of mothers on drug therapy are urged to document these events on an Adverse Drug Reaction Reporting Form (see Appendix 1 of the *Compendium of Pharmaceuticals and Specialties* or the Health Canada website at [http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index\\_adverse\\_report\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_adverse_report_e.html), or call toll-free 866-234-2345).

### Which references?

Mothers are often told to stop breastfeeding while on drug therapy because of inappropriate information about drugs in breastmilk and inaccessibility of reliable information on this topic. The *Compendium of Pharmaceuticals and Specialties* (CPS) product monographs may lead readers to inaccurate conclusions on the safety of drugs and breastfeeding, as manufacturers are not required to study a drug's presence in breastmilk.<sup>43</sup> The lavender pages of the CPS, however, contain an excellent section entitled "Drug use during lactation."<sup>36</sup> For

additional details consult *Medications in Mother's Milk*, a user-friendly book by Thomas Hale, a pharmacist and pharmacologist/toxicologist.<sup>19</sup> Table 5 offers other sources of information.

### Questions to consider

Given the misinformation and lack of information about the safety of drug use during breastfeeding, pharmacists can play an important role in providing advice both to other health professionals and to nursing mothers. By asking the following questions, and using their clinical knowledge of the drug, they can gather the information needed to make the most appropriate response.<sup>19</sup>

1. *Is the drug used in infants?* (e.g., fluconazole, given in doses to mothers at systemic treatment levels to treat *Candida* of the breast, is also used in infants) *In an exclusively breastfed infant, would the estimated dose to the infant be therapeutic?*<sup>19</sup>
2. *How old is the baby? Is he/she healthy?* (As neonates mature, their systems are more able to metabolize drugs; the liver of a new baby handling jaundice may have more difficulty metabolizing drugs such as sulfonamides; also see point #5 below)
3. *Is the drug orally bioavailable?* (e.g., omeprazole, insulin and some third-generation cephalosporins are labile in the stomach acid; interferons, insulin and heparins are too large to be absorbed orally by the infant from breastmilk)
4. *Does calcium in breastmilk interfere with absorption of the drug?* (e.g., tetracycline is deemed unavailable to the baby because it is chelated by calcium in breastmilk; oral absorption of ciprofloxacin is reduced in the presence of calcium)
5. *Could the baby have a non-dose-related reaction to the drug?* (e.g., babies with glucose-6-phosphate dehydrogenase [G6PD] deficiency may develop hemolytic anemia if exposed to sulfonamides; in babies with hyperbilirubinemia [severe jaundice], exposure to sulfonamides might delay clearance of jaundice or make it worse due to overloading liver enzymes)
6. *Is the benefit of drug therapy to the mother worth the estimated risk to the infant? What is the risk to the baby of the drug compared to the risks associated with the loss of breastfeeding and its benefits?*

### Risk/benefit assessment

Weighing risk versus benefit is a crucial final step in evaluating a therapy for a breastfeeding mother. In some rare instances, it may be necessary to stop breastfeeding. However, the pros and cons must be fully determined. Two risks often missed in this assessment are the risks of *not* breastfeeding<sup>11</sup> (see Table 1), and the companion risks of substituting artificial baby milks for breastmilk (see Table 3).<sup>20</sup> Aside from

**TABLE 4** Drugs for which second thinking, or specific monitoring, is advised <sup>\*,19,36,38</sup>

Amiodarone	monitor baby's thyroid as drug inhibits T4-T3 conversion; monitor cardiovascular function <sup>19</sup>
Atenolol/acebutolol	safety data is conflicting; choose alternate beta-blocker or monitor heart rate and body temperature <sup>19</sup>
Combination oral contraceptives	start a minimum of six weeks postpartum; monitor baby's weight gain and milk production or recommend progestin-only contraceptive as alternative <sup>22</sup>
Immunosuppressants	observe baby for signs of infection or abnormal blood count <sup>19</sup>
Lithium	monitor baby's hydration; once mother's therapy reaches steady state (approximately 10 days) monitor blood levels of lithium <sup>19,40</sup>
Miscellaneous	<ul style="list-style-type: none"> <li>• drugs that may cause drowsiness or sedation in mother (e.g., phenobarbital, ethosuximide, primidone<sup>36</sup>)</li> <li>• for drugs where no case reports or studies of drug in breastmilk exist, M/P ratio is &gt;1-5, or theoretical harm exists, clinician should assess physiochemical factors and risk to baby (e.g., retinoids)<sup>19</sup></li> </ul>

*\* This list is not exhaustive; other drugs may need to be monitored in breastfeeding infants. All drugs must be considered on an individual basis.*

the fact that use of artificial baby milk exposes the baby to foreign proteins and a food with no “vaccination” properties, a break in breastfeeding (even temporarily) also presents the mother with the challenge of pumping frequently to maintain her milk supply, and the risk that the baby will refuse the breast when the mother goes back to breastfeeding. Breastfeeding is much more than food for the baby; it also offers an opportunity for mother and infant to bond, which will be important in the child's future.<sup>2,44</sup> In fact, choosing to use artificial baby milks is classified as a “medical intervention,” according to the WHO Baby-Friendly Initiative.<sup>45</sup> According to the American Academy of Pediatrics, artificial baby milks should not be given to infants unless ordered by a physician when a medical indication exists.<sup>3</sup> This means that artificial baby milks are to be considered as seriously as any drug or other therapy with risks.

**Minimizing exposure**

Although most medications are believed to be safe for a mother to take while breastfeeding, exposure of the baby to drugs should be minimized. Many experts suggest that mothers should time the feedings to coincide with the time of the mother's lowest blood levels; however, since blood level troughs and milk level troughs are not synchronous and young babies (who are most at risk for side effects) feed on cue rather than according to any time schedule, this becomes impractical.<sup>19</sup> Minimizing exposure to the infant of medications is best done when therapy is chosen; some alternatives are suggested in Table 6.

If drug therapy is necessary but the mother does not wish to expose her infant to a drug, she can pump her breasts using a double pump system for maximum efficiency, and feed the baby previously pumped breastmilk

while she is on drug therapy. She can then pump and discard milk containing drug, and allow the baby to “comfort nurse” on the pumped breasts. Although the breasts are never “empty” even after pumping, the amount of milk is small and therefore drug exposure is negligible.

**Commonly asked questions**

**‘Can I have a drink of alcohol while I am breastfeeding?’** The Motherisk Clinic at Toronto's Hospital for Sick Children encourages mothers to abstain from alcohol while pregnant or breastfeeding.<sup>46</sup> The American Academy of Pediatrics considers alcohol a drug that is usually compatible with breastfeeding.<sup>38</sup> The International Lactation Consultant Association suggests mothers drink alcohol responsibly by minimizing exposure to the infant, and that an occasional drink of alcohol should not be harmful.<sup>47</sup>

For women who do not abstain from alcohol, use the nomogram in *Patient Self Care; helping patients make therapeutic choices*<sup>48</sup> or at [www.motherisk.org/updates/index.php?id=347](http://www.motherisk.org/updates/index.php?id=347) to advise a mother as to when her milk is alcohol-free. Use the nomogram along with suggestions in Table 7 to help counsel breastfeeding women on responsible alcohol use. Advise these women that pumping or hand-expressing alcohol-free milk beforehand prevents exposure to the infant of second-hand alcohol. However, since alcohol metabolism follows zero-order kinetics, “pumping and dumping” breastmilk, drinking coffee or drinking water will not speed up alcohol elimination.

**‘Is this antidepressant safe to take while I am breastfeeding?’** About 10-25 per cent of new mothers experience depression.<sup>49</sup> Antidepressants appear in breastmilk<sup>19</sup> and adverse effects appear benign.<sup>39</sup> Untreated depression in the mother is likely more harm-

ful to her baby than the potential side effects from commonly used antidepressants.<sup>49,50</sup> Breastfeeding causes mothers to be more resistant to stress than non-breastfeeding mothers.<sup>51</sup>

A recent review of 129 papers done by the Department of Pediatrics at Toronto's Hospital for Sick Children indicates that use of CNS-acting drugs does not appear to pose any major risks of immediate adverse effects to the infant, with the exception that newer drugs need to be further researched.<sup>39</sup> In another report, children who were exposed *in utero* to antidepressants did not exhibit any effect at up to seven years of age.<sup>52</sup> Given the proven benefits of antidepressant drugs and the risks of not receiving therapy, compared with the lack of proven danger of these drugs, it seems prudent to advocate the continuation of breastfeeding along with a judicious choice of antidepressant.

Of the SSRIs (selective serotonin reuptake inhibitors), sertraline has been studied the most,<sup>50</sup> and it appears to be a safe choice. Fluoxetine has the most evidence of safety in pregnancy and can be continued during breastfeeding.<sup>50,53</sup> In order to prevent the baby being born with a load of antidepressant with a long t<sup>1</sup>/<sub>2</sub>, recommendations are to reduce or eliminate fluoxetine prior to delivery (then restart postpartum) or switch to another antidepressant postpartum while breastfeeding.<sup>19</sup>

Talk therapy for depression is reported to be as effective and long-lasting as drug therapy and offers an alternative, non-invasive treatment modality for mothers for whom even small amounts of drug exposure to infants is a concern.<sup>54</sup> Encourage mothers to speak with their doctors about talk therapy as either an adjunct to drug therapy or, if their condition warrants, as replacement for drug therapy.

Mothers also ask about self-medicating for depression with St. John's wort. A Motherisk summary of case reports shows no untoward effects in the nursing infant.<sup>55</sup> However, this herb's validity for the treatment of depression has been questioned, as has the whole idea of self-medication for depression. Breastfeeding mothers who ask about St. John's wort should be referred to a licensed naturopathic doctor ([www.cand.ca](http://www.cand.ca)) or to their family doctor.

**‘I have to have an MRI scan and will be given some gadopentetate (gadolinium). Do I have to stop breastfeeding my baby for 48 hours after the test as I have been told?’** The answer is “no.” Gadopentetate has low oral bioavailability, a short t<sup>1</sup>/<sub>2</sub> and low milk levels, and it is used in infants for imaging. The American Academy of Pediatrics considers it to be usually compatible with breastfeeding.<sup>38</sup> A pharmacist can provide this updated safety information not only to the mother for discussion with her physician, but also to the local radiology laboratory.

**‘Can I use tooth whitener while breastfeeding? ‘Can I drink coffee or eat chocolate while**

**breastfeeding? 'Is it safe to use a nicotine gum or patch?' 'Is it safe to have a local anesthetic at the dentist while I am breastfeeding?'** The answer to all of these questions is "yes." Carbamide peroxide (a tooth whitener) releases hydrogen peroxide, which is broken down by the saliva and is safe during breastfeeding.<sup>19,56</sup>

Caffeine and chocolate (theobromine) in the diet are a problem only if baby shows side effects such as irritability.<sup>19,24</sup> If this happens, the mother should cut back on her intake or quit altogether.

Mothers who wish to quit smoking can be advised that both nicotine gum and patches are safer for their baby than exposure to the nicotine and other contaminants in cigarettes. Mothers weighing their smoking habit against the benefits of breastfeeding need to be aware that if they quit breastfeeding in order to smoke, their babies will be triply harmed. They won't get the health benefits of breastfeeding, there are risks (as described above) to using artificial baby milks, and the baby will still be exposed to secondhand smoke. If the mother is unable or unwilling to quit, she can be advised to smoke away from her baby, keep cigarettes per day to a minimum, and wait as long as possible after a cigarette before feeding.<sup>19,31,36</sup> Support her in continuing to breastfeed and refer her to a local smoking cessation program.

There are no studies on the use of bupropion for smoking cessation in breastfeeding women, but two case reports show undetectable bupropion breastmilk levels, indicating that it appears safe. However, more studies are needed.<sup>19,57</sup>

Dental anesthetic (most commonly articaine hydrochloride 4%) administered with epinephrine (a vasoconstrictor to slow transport into the bloodstream) is rapidly metabolized and is therefore unlikely to transfer into breastmilk.<sup>58,59</sup> Small amounts of topical lidocaine and prilocaine dental gel, used in dental procedures, are also not a problem.<sup>59</sup>

Given that mothers can safely breastfeed once awake after they have received epidurals or general anesthetics for Caesarean sections,<sup>60</sup> one can assume that dental anesthetics will be no hindrance to breastfeeding.

**'Can I take something for my cold/influenza/allergy symptoms when I am breastfeeding?' 'Can I have flu vaccine when breastfeeding?'** The answer to both these questions is "yes." One single-blind, randomized, crossover study of eight breastfeeding women showed that a single dose of pseudoephedrine 60 mg temporarily lowered milk supply in a breastfeeding mothers whose babies were over 12 months old.<sup>61</sup> More research is needed before considering pseudoephedrine to be contraindicated in breastfeeding.

Manufacturers recommend that adult

**TABLE 5** References for information on drugs, chemicals and herbs in breastmilk

<b>Books/CD-ROMs</b>
<ul style="list-style-type: none"> <li>• Briggs G, Freeman R, Yaffe S. Drugs in pregnancy and lactation, 6th ed. Baltimore, MD: Lippincott Williams &amp; Wilkins; 2002.</li> <li>• Hale T. Medications and mother's milk, 11th ed. Amarillo, TX: Pharmasoft Publishing; 2004.</li> <li>• Humphrey S. The nursing mother's herbal. Minneapolis, MN: Fairview Press; 2003.</li> <li>• Ito S, Brochet MS. Drug use during lactation (lavender pages). In: Compendium of Pharmaceuticals and Specialties. Ottawa, ON: Canadian Pharmacists Association; 2005.</li> <li>• Peddlesden J. Infant nutrition. In: Patient self care (PSC): Helping patients make therapeutic choices. Ottawa, ON: Canadian Pharmacists Association; 2002.</li> </ul>
<b>Personal digital assistants</b>
<ul style="list-style-type: none"> <li>• Hale T. Medications and mother's milk, 11th ed. Amarillo, TX: Pharmasoft Publishing; 2004 (<a href="http://www.ibreastfeeding.com">www.ibreastfeeding.com</a>).</li> <li>• Briggs G, Freeman R, Yaffe S. Drugs in pregnancy and lactation, 6th ed. for PDA; a reference guide to fetal and neonatal risk (<a href="http://www.intl.elsevierhealth.com">www.intl.elsevierhealth.com</a>).</li> </ul>
<b>Telephone/DI centres</b>
<ul style="list-style-type: none"> <li>• The Motherisk Clinic, Hospital for Sick Children, Toronto, ON 416-813-6780</li> <li>• Local or regional drug information centres</li> </ul>
<b>Web resources</b>
<ul style="list-style-type: none"> <li>• Motherisk: <a href="http://www.motherisk.org">www.motherisk.org</a> and search Motherisk Updates</li> <li>• American Academy of Pediatrics. The transfer of drugs and other chemicals into human milk. <i>Pediatrics</i> 2001;108(3):776-89. <a href="http://aappolicy.aappublications.org/cgi/content/full/pediatrics;108/3/776">http://aappolicy.aappublications.org/cgi/content/full/pediatrics;108/3/776</a>.</li> <li>• 'Bulletin on Drugs and Breastfeeding from Children and Women's Hospital BC: <a href="http://www.rcp.gov.bc.ca">www.rcp.gov.bc.ca</a> (Click on 'What's New' tab; go to Clinical Pharmacy Bulletin)</li> </ul>

**TABLE 6** Ways to minimize drug exposure to a breastfed infant<sup>19,48</sup>

<ul style="list-style-type: none"> <li>• If possible, delay therapy until after weaning (e.g., treat hyperthyroid condition with propylthiuracil until mother can undergo ablation with I<sup>131</sup> [radioactive iodine]).</li> <li>• Use a drug with published literature on use in breastfeeding mothers and a safe profile for the breastfeeding baby.</li> <li>• Choose a non-drug therapy where appropriate, such as acupuncture, massage, physiotherapy, talk therapy, chiropractic, nasal strips for congestion instead of pseudoephedrine tablets.</li> <li>• Use a topical route of drug administration rather than systemic or oral, where possible, to lessen absorption into the bloodstream and the mother's milk (e.g., diclofenac gel versus oral for pain; antihistamine eye drops instead of tablets for allergy symptoms; nasal corticosteroids for allergic rhinitis versus oral antihistamines).</li> <li>• Choose the member of a drug family with the shortest t<sub>1/2</sub> and fewest active metabolites to prevent accumulation in a young infant, or choose a drug where the RID is &lt;10% of the maternal dose.<sup>15</sup></li> </ul>
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RID = relative infant dose

doses of OTCs used to treat or prevent the common cold (e.g., zinc lozenges, vitamin C) would not harm a breastfed baby.<sup>62</sup> A proprietary extract of *Panax quinquefolium L.* (American ginseng), which is used for the prevention of acute respiratory illness, would seem to be safe for ingestion by breastfeeding mothers. It is comprised of more than 90 per cent of saccharides (very large molecules) that exert an effect on the mother's immune system in her gastrointestinal tract but are not absorbed into her bloodstream.<sup>63</sup> Non-sedating antihistamines such as loratidine, cetirizine

and fexofenadine are safe to use for allergies despite package warnings to the contrary, as are antihistamine and cromolyn eye drops.<sup>36,38</sup> Manufacturers' recommended adult doses of the older sedating antihistamines can also be used safely.<sup>36,38</sup> If sedating antihistamines are used, however, the baby should be monitored for drowsiness or paradoxical stimulation.<sup>19</sup> Ibuprofen and acetaminophen in manufacturers' recommended adult doses are safe to use for pain and fever relief.<sup>19</sup> Flu vaccine is safe for breastfeeding mothers, as influenza vaccine is now recommended for infants.<sup>64</sup>

### The pharmacist's role

Pharmacists can provide support for breastfeeding and information on drug pharmacokinetics to help a mother participate in her decision on drug therapy while she is breastfeeding her baby. As drug manufacturers are not required to provide studies on the presence of drugs in human milk, pharmacists must use other references and sources beyond the drug monograph.

The "warm chain" for breastfeeding describes the support and skilled care given to the breastfeeding mother: showing her what to do, building her confidence, and protecting her from practices harmful to the breastfeeding relationship with her baby.<sup>65</sup>

In maintaining the 'warm chain,' pharmacists play an important role in minimizing therapeutic interventions<sup>3</sup> or other interventions that interfere with the mother's breastfeeding relationship with her baby, and the right of the baby to the great benefit of its mother's milk. Pharmacists can obtain further education about breastfeeding, its protective qualities and promotional suggestions through programs at Canadian colleges, or less formally by joining the Canadian Pharmacists' Association

### TABLE 7 Recommendations to breastfeeding mothers for drinking alcohol responsibly<sup>47,48</sup>

- Before drinking alcohol, hand express or pump ahead a supply of alcohol-free milk.
- Dilute alcoholic drinks with water, juice or milk/ice cream.
- Drink slowly, sip and pace your drinking, spacing drinks a minimum of two to three hours apart.
- Eat before and while drinking (absorption of alcohol is three times slower with a meal of carbohydrate, protein and fat).
- Choose non-alcoholic drinks that resemble alcohol-containing drinks.
- Have a drink of water on the go along with the alcoholic drink.

(CPhA)'s Practice Interest Group on Breastfeeding (see Table 2).

### Summary

All medications penetrate into breastmilk to some extent.<sup>19,36,38</sup> However, the RID in most cases is usually less than one per cent of the mother's dose, and most are therefore safe for a mother to use when she is breastfeeding.<sup>7</sup> At the same time, caution should be used given the lack of data available for use of drugs in infants. A number of principles can be followed when choosing the best drug therapy. Drug therapy should be used in the mother only when necessary. Choose drugs whose presence, absence or level in milk has been previously recorded. Use

the drug with the shortest  $t_{1/2}$  and least active metabolites in its class to prevent potential accumulation, and focus on drugs that are highly protein-bound.

Supporting breastfeeding has positive implications to individual and community health, and to the cost of health care.<sup>12,23</sup> Providing other healthcare professionals with information on the safety of drugs during breastfeeding protects and promotes the practice of breastfeeding, and follows the CPhA's 2001 Position Statement on Breastfeeding and Infant Nutrition.<sup>66</sup>

*References can be found on page 25 of this issue of Pharmacy Practice.*

### Questions

**1 According to Health Canada, exclusive breastfeeding is defined as:**

- a) breastmilk only, unless artificial baby milk is medically indicated
- b) breastmilk only, except for medicinal drops or syrups
- c) at least 95 per cent of the baby's food comes from breastmilk up to and including six months
- d) a and b

**2 Sylvia is three months postpartum, and breastfeeding her baby Emma. Her doctor is suggesting that she wean Emma now, to enable her to have thyroid ablation using radioactive iodine<sup>131</sup> next month. The treatment was postponed when Sylvia became pregnant last year. Sylvia has asthma and struggles to keep her anemia under control. What is the best option for Sylvia and the baby?**

- a) Take propylthiuracil for the hyperthyroid condition and wean Emma, as this drug is not safe during breastfeeding.
- b) Take the <sup>131</sup>I therapy now, as this therapy is important for her health, and continue to breastfeed.
- c) Take propylthiuracil treatment now and continue to breastfeed exclusively for at least three more months; then wean and take the <sup>131</sup>I therapy.
- d) Rent a breastpump and pump milk ahead of time, so she will have enough frozen to feed Emma while she has the <sup>131</sup>I therapy next month.

**3 If Sylvia decides to wean now, which of the following risk factors, if any, will come into play for her and Emma?**

- a) risk of delaying the <sup>131</sup>I therapy for Sylvia
- b) risk of early exposure to cow or soy protein in artificial baby milks and subsequent increase in allergy risk in Emma, since there is a family history
- c) risk of Sylvia's menses returning, exacerbating her anemia, not going back to her pre-pregnant weight as quickly, and increasing her risk of breast cancer from not breastfeeding as long
- d) b and c
- e) there are no risk factors for her or her baby

**4 Once ingested by a breastfeeding mother, passive diffusion from her bloodstream causes drugs to be in her breastmilk. The only way that the drug can leave this compartment is by removing the milk through breastfeeding or pumping the milk out.**

- a) True
- b) False

**5 Which of the following would generally be considered safe for use in breastfeeding mothers?**

- a) metronidazole
- b) fexofenadine
- c) carbamide peroxide
- d) b and c
- e) all of the above

**6 Why would one not rely solely on an official manufacturer's monograph to check for safe drug use in a breastfeeding mother?**

- a) Drug manufacturers do not have to conduct

studies on a drug's appearance in breastmilk for licensure by Health Canada.

- b) Drug manufacturers do not report the RID for a drug.
- c) New information, from drug studies conducted after the drug was licensed, may not be in the monograph.
- d) a and b
- e) all of the above

**7 You are working the evening shift in a community pharmacy and need to find out if trimethoprim-sulfamethoxazole tablets 500 mg bid for five days are safe for a breastfeeding mother of a six-month-old. The mother read the patient print-out that came with her prescription and it says the drug may be unsafe in breastfeeding. Which reference could you check?**

- a) *Bulletin on Drugs and Breastfeeding* from Children and Women's Hospital British Columbia
- b) the lavender pages of the CPS
- c) website of the American Academy of Pediatrics
- d) any or all of the above

**8 Which of the following statements outline(s) some practical ways to minimize exposure of a breastfeeding infant to a drug?**

- a) Give the lowest dose of drug necessary and suggest that the mother pump and dump her milk at least four times daily.
- b) Treat a breastfeeding mother with drugs only when necessary, and choose a drug from a

## Questions

therapeutic category that has an RID of less than 10 per cent of the mother's dose.

- c) Choose a drug with low plasma protein binding, and low overall side effects.
- d) b and c

**9** Ann comes into your pharmacy and asks you what herb will increase her milk supply. She is the mother of Sam, a two-month-old infant who has been breastfed exclusively up until now. You know the family well and know that Sam was three weeks premature, and you see that he is using a soother. Ann's drug profile tells you she has allergies/asthma and also had a combination oral contraceptive prescription filled three weeks ago. The first thing you should do is:

- a) Suggest that she supplement 1 ounce of artificial soy baby milk after every feed, as soy is less allergenic than cow milk formula, and thus is safer with the family history of allergy.
- b) Recommend that Ann see a lactation nurse, lactation consultant or the local La Leche League for suggestions on her milk supply problems.
- c) Ascertain why she thinks her milk supply is down, and also ask if Sam's weight gain has been checked lately by either a health nurse or the family doctor.
- d) Provide a list of local breastfeeding experts and also suggest that Ann see her family doctor, as combination oral contraceptives have been known to affect milk supply.

**10** The second most appropriate action in helping Ann would be which of the options in question number 9?

- a) Suggest that she supplement 1 ounce of artificial soy baby milk after every feed, as soy is less allergenic than cow milk formula, and thus is safer with the family history of allergy.
- b) Recommend that Ann see a lactation nurse, lactation consultant or the local La Leche League for suggestions on her milk supply problems.
- c) Ascertain why she thinks her milk supply is down, and also ask if Sam's weight gain has been checked lately by either a health nurse or the family doctor.
- d) Provide a list of local breastfeeding experts and also suggest that Ann see her family doctor, as combination oral contraceptives have been known to affect milk supply.

**11** Ann thanks you for your suggestions but still wants to try a herb for her milk supply. You check the label of the mother's milk tea on the shelf in the complementary medicines area, and note that it contains one herb that might be contraindicated for Ann. That herb would be:

- a) dill seed
- b) red raspberry leaf
- c) fenugreek
- d) caraway

**12** Ann returns one week later. She has taken the steps you suggested. Sam's weight gain is now improving, Ann has begun nursing him more often

and soothes him at the breast rather than with the soother. She is coming in to have two new prescriptions filled. The most appropriate prescription might be:

- a) norethindrone 1 tablet daily, and domperidone 20 mg qid for three weeks
- b) medroxyprogesterone depot injection and domperidone 10 mg bid for three weeks
- c) cabergoline 1 mg (2 x 0.5 mg tablets) immediately and norethindrone 1 tablet daily
- d) a or b

**13** A 33-year-old first-time mother is being treated successfully during her pregnancy for depression, using fluoxetine 20 mg daily. The attending physician asks your advice on switching her from fluoxetine to sertraline after the baby is born. The most appropriate course(s) of action is/are:

- a) Taper fluoxetine during her third trimester to prevent the baby from being born with a load of drug to handle on its own, then continue with fluoxetine postpartum, adding talk therapy as well.
- b) Continue with the fluoxetine now and switch postpartum to sertraline, adding talk therapy as well.
- c) Continue with fluoxetine now and, postpartum, gradually replace drug therapy with talk therapy, as the breastfeeding hormones may lower her stress.
- d) any of the above

**14** A woman calls you just before Saturday closing and says she does not want to give her three-month-old baby any alcohol, so asks how long she will have to wait to breastfeed her baby if she drinks beer tonight at a party. What questions might you need to ask her before giving an answer?

- a) How many beers do you expect to consume?
- b) Approximately how much do you weigh?
- c) Do you have any alcohol-free breastmilk stored in the fridge or freezer?
- d) all of the above
- e) Don't bother to ask questions; suggest she buy some artificial baby milk to use so she can have as many drinks as she likes.

**15** Which of the following references can you use to most accurately answer this woman's questions about alcohol in breastmilk?

- a) The Motherisk Updates <http://www.cfpc.ca/cfp/2002/aug/vol48-aug-clinical-1.asp>
- b) *Drugs in Pregnancy and Lactation* by Briggs, Freeman and Yaffe
- c) *Goodman & Gilman's Pharmacological Basis of Therapeutics*
- d) *Patient Self Care: helping patients make therapeutic choices* (chapter 32, Infant Nutrition)
- e) a and d

**16** A baby would not need to be weaned if the mother requires gadopentatate, a radioopaque chemical ingested for imaging, because:

- a) it has a short half-life

- b) there is minimal oral absorption by the mother into her bloodstream and milk
- c) it is used in imaging in infants
- d) all of the above

**17** Which of the following statements is correct regarding predicting low or negligible levels of these drugs get to a breastfed baby via human milk?

- a) interferon beta 1a because it is highly protein bound in mother's plasma
- b) enoxaparin (a heparin) because it is a very large molecule
- c) warfarin because it is destroyed by the lysozyme in the milk
- d) ciprofloxacin because it is chelated by the lactoferrin in the milk

**18** A young mother is taking lithium carbonate for mania. What would be a consideration when she is breastfeeding her new baby while on lithium therapy?

- a) Carefully watch the baby's weight gain and hydration status.
- b) Monitor the baby's serum levels of lithium.
- c) a and b
- d) Suggest a drug holiday for the first three months of breastfeeding and use an alternate treatment during that time.

**19** Over-the-counter cough and cold medications, used according to the manufacturer's recommended adult dosage, would not harm a breastfeeding baby.

- a) True
- b) False

**20** A mother of a breastfed four-month-old asks you why her pumped milk looks green in colour. On checking her profile, you suggest that the most plausible reason for this colouration could be:

- a) the protein supplement powder she bought last week
- b) minocycline taken for her acne
- c) self-medication with alfalfa supplement
- d) none of the above

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